Medicines Reconciliation Research in Young Patients (MERRY)

A series of exploratory studies and service evaluations on the clinical significance of medicines reconciliation in children upon transitions in care between home and hospital

Chi Huynh

November 2013

UCL

University College London School of Pharmacy

Submitted in part fulfilment of the requirement for the Doctor of Philosophy degree

Plagiarism statement

This thesis describes research conducted in the School of Pharmacy, University College London between October 2010 and November 2013 under the supervision of Professor Anthony Smith, Dr Yogini Jani, Stephen Tomlin and Professor Ian Wong. I certify that the research described is original and that any parts of the work that have been conducted by collaboration are clearly indicated. I also certify that I have written all the text herein and have clearly indicated by suitable citation any part of this dissertation that has already appeared in publication.

Signature

27th November 2013

Date

Abstract

Medication discrepancies occurring at the interfaces of care between hospital and home may cause patient harm. Medication reconciliation (also known as medicines reconciliation) has been suggested as an intervention that may reduce discrepancies. National guidance has made it mandatory for hospitals in the UK to have Medication Reconciliation policies in place for adult patients admitted to hospital. This policy excluded children aged less than 16 years. This thesis aimed to investigate the incidence and potential clinical outcome of medication discrepancies occurring across the interface of care for hospitalized children from admission, discharge and postdischarge.

At hospital admission across four UK paediatric settings it was observed that 32% (95% CI = 26.1 - 37.8%) of 244 paediatric patients had at least one potentially clinically significant unintended discrepancy between their pre-admission medication and initial admission medication order in the absence of pharmacist-led medication reconciliation. At discharge, approximately one third of 142 discharge letters reviewed for accuracy over 5 weeks had at least one discrepancy which were detected and corrected by a pharmacist. Post-discharge follow up of patients revealed that 7.7% (95% CI 1.1 – 16%) of patients experienced at least one discrepancy between what was prescribed by the hospital at discharge in comparison to what was prescribed by the GP.

Qualitative observations revealed that more than one source of information were required to reconcile medication at admission and GP records did not provide a complete medication history. Post discharge observations highlighted that hospital discharge letters were not always clear resulting in discrepancies between the intended discharge medication list and GP record.

This work provides evidence that children aged less than 18 years of age require medication reconciliation when transferring between primary and secondary care. Preventable interventions are required across the care settings to ensure patient safety and to reduce chances of preventable adverse events.

Acknowledgements

With great pleasure, I want to thank all who have supported and encouraged me to journey through these three years in research.

I want to thank Dr Yogini Jani, Stephen Tomlin, Professor Ian Wong and Professor Anthony Smith for their academic, clinical and pastoral support and guidance throughout the PhD. In addition I want to thank my examiners Professors Claire Anderson and Professor Felicity Smith for their guidance.

My interest in pharmacy practice research was formed at the School of Pharmacy, University of London, where I met Professor Wong who taught me what research was about and provided me with an opportunity to conduct research as an undergraduate and also continue with research by providing me with this PhD studentship.

I am grateful to Stephen Tomlin and Dr David Terry for providing me with an opportunity to research in the Neonatal and Paediatric Pharmacists Group funded multisite project on admissions medication reconciliation. I want to thank the multisite study team at Birmingham Children's Hospital, North Staffordshire hospital, Leeds Royal infirmary, and the Evelina Children's Hospital in London.

I want to acknowledge Dr Maisoon Ghaleb, who provided the opportunity to explore medication reconciliation at discharge through the small grant from the University of Hertfordshire and also to Miss Ellisha Mortazaee and Miss Chea-Xin Lim who worked with me on this project.

Thanks are due for the MERRY-PD team (Dr Yogini Jani, Dr Maisoon Ghaleb, Professor Ian Wong, Stephen Tomlin) for their support and contributions to developing the project. I want to thank the following organisations: - Pharmacy Practice UK for their funding, Guy's and St Thomas NHS Foundation Trust for acting as sponsors, the NIHR Medicines for Children Research Network and the research nurses from Evelina Children's Hospital. I also want to thank all the parents, carers and patients who have taken part in the studies for my thesis and research.

I thank the staff and students at the Centre for Paediatric Pharmacy Research, Dr Catherine Tuleu, Dr Macey Murray, Yingfen Hsia and especially my PhD colleagues Noor Al-Mandil, Aisha el-Turki, Noha Iessa, Norkasihan Ibrahim and Mariam Wahab.

I also want to thank my colleagues from the University of London Union St John Ambulance LINKS unit for their support.

On a personal note, I want to thank my family and friends for their continued support, patience and understanding during my 10 years at university.

Finally, I want to thank my church, fellow Christian brothers and sisters and thank God, my LORD and saviour who has always been there through this journey and been ever loving and unchanging.

Publications

Parts of the thesis have been published and presented on the following occasions: -

Peer reviewed journals

Huynh, C., Jani, Y., Wong, I. C. K., Dewchand, B. and Tomlin, S. 2013. What is the current practice of medicines reconciliation in children nationally in the UK? International Journal of Pharmacy Practice, 21, pp. 62-65

Huynh, C., Wong, I.C.K., Tomlin, S., Terry, D., Sinclair, A., Wilson, K., Jani, Y. 2013. Medication discrepancies at transitions in pediatrics: a review of the literature. Pediatric Drugs, 15, pp. 203-215.

Published oral/poster presentations

Huynh, C., Jani, Y., Wong, I.C.K., Ghaleb, M., Lo, A., Crook, J., Tandle, V., Tomlin, S. 2013. Clinical significance of medication discrepancies in children post hospital discharge across five hospitals in England. International Journal of Pharmacy Practice, 21, pp. 10-1 (oral).

Huynh, C., Tomlin, S., Jani, Y., Wong, I., Ghaleb, M. 2013. Post discharge follow up of children on long term medications. Archives of Disease in Childhood, 98 pp. e1 (poster)

Huynh, C., Mortezaee, E., Tomlin, S., Jani, Y., Ghaleb, M., Wong, I.C.K. 2012 Medicines reconciliation at the point of hospital discharge for children. Archives of Disease in Childhood 97, pp. e7-e8 (poster)

Huynh, C., Jani, Y., Tomlin, S., Terry, D.R.P., Sinclair, A., Wilson, K.A., Wong, I.C.K. 2012. Epidemiology of medication discrepancies upon hospital admission in children – a systematic review. Archives of Disease in Childhood, 97, pp. e7 (poster)

Huynh C, Terry D, Tomlin, S., Jani, Y., Haley, H., Smith, R., Lowey, A., Sinclair, A., Wilson, K., Wong, I.C.K. 2012. The Clinical Significance of medicines reconciliation in children admitted to hospital. Pharmacoepidemiology and Drug Safety, 21, pp. 792 (oral)

Unpublished oral presentations

The 6th Asian Conference on Pharmacoepidemiology (ACPE) and 2011 Annual Meeting of the Committee of Pharmacoepidemiology of the Chinese Pharmaceutical Association (AMCP-CPA); Beijing, China -October 28 – 30, 2011

Huynh, C., Mortezaee, E., Tomlin, S., Jani, Y., Ghaleb, M., Wong, I.C.K. Medicines reconciliation at the point of hospital discharge for children.

The 6th Asian Conference on Pharmacoepidemiology (ACPE) and 2011 Annual Meeting of the Committee of Pharmacoepidemiology of the Chinese Pharmaceutical Association (AMCP-CPA); Beijing, China -October 28 – 30, 2011

Huynh C, Terry D, Tomlin, S., Jani, Y., Haley, H., Smith, R., Lowey, A., Sinclair, A., Wilson, K., Wong, I.C.K. Medicines reconciliation upon hospital admission in children – A UK multisite study.

Tab	e	of	Co	nte	nts

Plagiarism statement	1
Abstract	2
Acknowledgements	4
Publications	6
Table of Contents	8
List of Tables	14
List of Figures	16
Abbreviations	17
Chapter 1 - Introduction	19
1.1 The origins of medication reconciliation, transitions in care and key documents and guidance	20
1.2 Medication reconciliation	22
1.2.1 Medication reconciliation definitions	22
1.2.2 Role and healthcare professional involvement in reconciling medication	26
1.2.3 Definitions of transitions in care medication discrepancies	27
1.3 Medication reconciliation specific publications, methodology and results in adults	33
1.3.1 A discussion on the review conducted in adults - NICE Commissioned Medication reconciliation systematic review by Campbell et al 2007	33
1.3.2 Reported incidences and rates of medication discrepancies in observational studies upon hospital admission, discharge and post discharge in adults	35
1.3.3 Summary	36
1.4 The difference between paediatric and adult health services and medicines use studies conducted in children	37

1.4.1 What is the difference between children's health services and adults?	39
1.4.2 Previous paediatric studies and prescribing error. Has medication reconciliation been part of previous studies?	40
1.5 Literature review on the epidemiology of medication discrepancies upon hospital admission, transfer and discharge in children	42
1.5.1 Methods	43
1.5.2 Results	47
1.5.3 Discussion	65
1.6 Main aims and thesis research questions	70
1.6.1 Research Question	70
1.6.2 Overall aim	71
1.7 PhD candidate's contribution and overall methodological design for the thesis	72
1.7.1 PhD candidate's background and contribution to the thesis	72
1.7.2 Overall methodological design of the thesis studies	73
1.7.3 Assessment of the methodological approach employed for the thesis studies	75
Chapter 2 - A multi-centre study of pharmacy led medication reconciliation upon hospital admission in children	81
Aims and Objectives	82
2.2 Multi-site study – Identification of medication discrepancies upon hospital admission for children and clinical significance	83
2.2.1 Methods	84
2.2.2 Results	90
2.2.3 Discussion	98
2.2.4 Conclusions	99
2.3 Defining, development and piloting of a derived medication reconciliation pathway and form	101
2.3.1 Aims and objectives	.101

2.3.2 Method	102
2.3.3 Results	109
2.3.4 Discussion	129
2.3.5 Conclusions	131
2.4 Evaluation of the derived medication reconciliation pathway – Focus Group	
2.4.1 Background	132
2.4.2 Aims and objectives	132
2.4.3 Method	133
2.4.4 Results and Discussion	136
2.4.5 Conclusion	161
2.5 The feasibility of a randomised control trial for an admissions reconciliation intervention for children – a survey of paediatric pharmacists on current practice of medication reconciliation	162
2.5.1 Background and purpose	162
2.5.2 Methods	163
2.5.3 Results	164
2.5.4 Discussion	167
2.5.5 Limitations	167
2.5.6 Conclusion	168
2.6 Summary of project findings, implications for practice, limitations and recommendations	169
2.6.1 Summarised project findings	169
2.6.2 Study Limitations	170
2.6.3 Implications and importance for clinical practice and policy	171
2.6.4 Suggested further studies and actions	172
Chapter 3 - Medication reconciliation at the point of hospital discharge in children	174

3.1 Aims and objectives175
3.1.1 Aim175
3.1.2 Objectives
3.2 Methods
3.2.1 Stage 1 Hospital Discharge prospective review of drug charts176
3.2.2 Stage 2 GP receipt and reconciliation process
3.3 Results
3.3.1 Stage 1 hospital discharge180
3.3.2 Stage 2 GP receipt and reconciliation process
3.4 Discussion190
3.5 Conclusion
Chapter 4 – Medication Reconciliation Research in Young patients followed up from hospital to home194
4.1 Background
4.2 Aims and objectives
4.2 Aims and objectives
 4.2 Aims and objectives

4.4.1 Stage 1 Recruitment of parents/patients for follow-up	.208
4.4.2 Stage 2 Root cause analysis of potentially harmful unintentional post discharge discrepancies	.241
4.4.3 Stage 3 A focus group of healthcare professionals' perceptions and experiences of post discharge discrepancies in children post hospital discharge	.252
4.5 Discussion	.271
4.6 Conclusions	.274
Chapter 5 - Discussion	.275
5.1 Suggestions for improving and standards for medication reconciliation upon hospital admission, and implementing interventions for post discharge in children	282
5.2 Strengths and limitations of the thesis	
5.3 Recommendations for clinical service development	
5.4 Suggested future areas for further study	
5.5 Conclusion	
References	.294
Appendices	.303
Appendix A – Pre-assessment study form used in admissions study (Chapter 2)	.303
Appendix B – Data collection form used for Admissions study (Chapter 2)	.304
Appendix C – Pharmacist led medication reconciliation in children – pathway intervention (Admission)	.313
Appendix D – Pharmacist led medication reconciliation in children intervention – Data collection form	.317
Appendix E – Medication reconciliation upon hospital admission multisite admission study – Focus group moderator's question guide	.319
Appendix F – 14 day post hospital discharge interview of GP surgery staff schedule: - Questions for GP Practice manager /administrator	.322

Appendix G – Data capture form for GP surgery reception staff interview
Appendix H – Initial thematic framework for the telephone follow up and interview of GP surgery staff 14 days post hospital discharge (non exhaustive and based on initial familiarization with data)
Appendix I – Finalized thematic framework for the telephone follow up and interview of GP surgery staff 14 days post hospital discharge (non exhaustive and based on initial familiarization with data)
Appendix J – Sample of Parent/Patient information leaflets
Appendix K – MCRN Young person's advisory group feedback
Appendix L – Consent forms (for parent/carer/patient)
Appendix M – Sample Assent form
Appendix N – Sample data collection form for Post discharge follow up349
Appendix O – MERRY-PD – Standard Operational Procedure for contacting GP351
Appendix P – Focus group invitation
Appendix Q – Focus group Participant information leaflet
Appendix R – Moderator's guide to the focus group

List of Tables

Table 1	Definitions of medication reconciliation	24
Table 2	Details of studies excluded during the data extraction stage of the literature review	49
Table 3	Characteristics of studies included in the literature view	52
Table 4	Details of studies reporting a medication reconciliation intervention	59
Table 5	Medication orders and "GPRx V AMO(u)" unintentional discrepancies categorized per BNF chapter	96
Table 6	Stratified results for each of the four study sites	97
Table 7	Number and percentage of matches for each source of information to when compared against the pharmacist's recommended therapy	110
Table 8	Examples of GPRx v AMO(u) unintentional discrepancies where deviating from the GP record would have been beneficial rather than harmful	113
Table 9	Unintentional discrepancies where the pharmacist recommendation did not match any source or the AMO	115
Table 10	GP usage during medication reconciliation intervention across the four study sites	123
Table 11	Number of sources used for each drug finalised on the medication history per BNFC chapter classification	125
Table 12	Summary of the discrepancy findings comparing the two methods "GPRx v AMO" and "Pharmacist v AMO"	127
Table 13	Collated results of "GPRx v AMO", "Pharmacist v AMO" discrepancy from the multisite study and pilot medication reconciliation intervention data	129
Table 14	Initial thematic coding framework	135
Table 15	Example of a minor severe discrepancy on a hospital discharge letter	181
Table 16	Example of a moderately severe discrepancy on a hospital discharge letter	181

Table 17	Demographics of patients followed up post hospital discharge.	209
Table 18	Reasons why parents recruited were not followed up post hospital discharge	210
Table 19	Medication discrepancy details identified from the post hospital discharge follow-up of parents of paediatric patients	212
Table 20	Examples of unintentional, intentional and unknown discrepancies post hospital discharge	213
Table 21	Thematic summaries of post hospital problems, actions to address the problems and mechanism for obtaining further supplies of medication	215
Table 22	Parent's report of the time taken for the medication to be ordered into the community pharmacy	229
Table 23	Description and examples of parents' comments on informing the GP of hospital changes	236
Table 24	Summary of possible root causes of unintentional discrepancies	243

List of Figures

Figure 1 -	- Medication Discrepancy Tool (from Smith et al 2004)	51
Figure 2 -	- Search Procedure and detailed criteria used to select the papers4	-8
Figure 3 -	- A summary flow diagram of the overall chronological methodological design of the thesis studies7	'4
Figure 4 -	- Classification procedure of "GPRx v AMO" discrepancies9	12
Figure 5 -	- Clinical assessment process of the 342 "Pharmacist v AMO" unintentional discrepancies11	8
Figure 6 -	- The main themes of the coding framework for the GP surgery post hospital discharge interview18	4
Figure 7 -	- Summary of the methodological approach and expected outcomes for the MERRY-PD study20	00

Abbreviations

ADE	Adverse Drug Event
ΑΜΟ	Admission Medication Order (Initially prescribed drug chart prior to pharmacist screening)
BNF	British National Formulary
BNFC	British National Formulary for Children
BPMDL	Best Possible Medication Discharge List
BPMH	Best Possible Medication History
CHaMP	Child Health and Maternity Partnership
CDSR	Cochrane Database of Systematic Reviews
CENTRAL	Cochrane Central Register of Controlled Trials
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CQC	Care Quality Commission
DARE	Database of Abstracts of Reviews of Effects
DH	Department of Health
GP	General Practitioner
GPRxs	GP current drug history
ICU	Intensive Care Unit
IHI	Institute of Healthcare Improvement
MDT	Medication Discrepancy Tool
MUR	Medicines Use Review
mg	milligrams
ml	millilitres

- **NICE** National Institute of Health Care Excellence
- NPC National Prescribing Centre
- NPPG Neonatal and Paediatric Pharmacists Group
- **NSF** National Service Framework
- PAM Pre-Admission Medication list
- PCT Primary Care Trust
- POD Patient's Own Drug
- SCI Science Citation Index
- **SSCI** Social Science Citation Index
- TTA To Take Away (Hospital discharge letter)
- NPSA National Patient Safety Agency
- UK United Kingdom
- US United States of America
- WHO World Health Organisation

Chapter 1 - Introduction

1.1 The origins of medication reconciliation, transitions in care and key documents and guidance

Adverse Drug Events (ADEs), injuries involving medication use, which may result in patient harm, are estimated to affect between 7.5 and 10.4 percent of hospitalized patients in developed countries. ADEs are estimated to cost the healthcare system billions of US dollars globally, with some studies suggesting that ADEs may cause 140,000 deaths a year in the US alone. It is estimated that between 28 and 56 percent of these ADEs are preventable (WHO 2008).

In the US, the Institute of Health Improvement (IHI) launched a "100,000 lives campaign" in 2004, aimed at making healthcare safer and more effective. One of the six steps suggested in the campaign was to use medication reconciliation as an intervention to reduce preventable ADEs, based on the evidence that over half of all hospital medication errors occurs at the interfaces of care (Institute for Health Improvement 2008; Rozich and Resar 2001). Medication reconciliation in the UK) has been defined as the process of creating the most accurate list possible of all medications a patient is taking. The list should include the name of the medication, dose, directions, frequency and route and comparing this against the physician's admission, transfer, and discharge orders with the aim of providing the right medications to the patient at all transition points within the hospital (Institute for Healthcare Improvement 2008).

The problem of the occurrence of 'interface of care' related medication errors, which may result in a preventable ADE is not just a problem for the In 2006, the World Health Organization Patient US, but a global issue. Safety collaborating body included medication reconciliation as one of the five standardized patient safety solutions (so called "high 5s") to achieve measurable, significant and sustainable reductions in challenging patient safety problems. Countries such as Canada, the US and UK have incorporated medication reconciliation as a priority area for national patient safety initiatives and goals, but few define the patient populations (Accreditation Canada 2012; The Joint Commission Sentinel Event Alert, 2006; NICE 2007). National guidance in the UK advocates medication reconciliation on admission to hospital for all adult patients, but excludes children under the age of 16 years (NICE 2007) whilst medication errors, particularly dosing errors, are common in children (Ghaleb et al 2010; Wong et al 2004), and have been shown to be three times more likely to be harmful than in adults (Kaushal et al 2001). The role of medication reconciliation in this patient group is unclear.

1.2 Medication reconciliation

1.2.1 Medication reconciliation definitions

Medication reconciliation (also known and referred to as Medicines Reconciliation in the UK) is a process designed to prevent medication errors at patient transition points (WHO 2007), and involves: -

- Recording the most complete and accurate list possible at the time or "Best possible Medication History" (BPMH) that the patient has been taking. This is also called the "home medication list"
- Comparing this list against the admission, transfer and/or discharge orders when writing medication orders; identifying and bringing any discrepancies to the attention of the prescriber; and, if appropriate, making changes to the orders and documenting them
- Updating the list as new orders are written to reflect all of the patient's current medications
- Making sure that the list is given to the next provider of care whenever the patient is transferred or discharged and providing a copy of the discharge summary to the patient

In England, the National Institute for Health Care Excellence (2007), specifies medication reconciliation as: -

 Obtaining information on a patient's medication history using the most up to date and accurate sources to establish a current and complete list of medicines. The main source is the GP repeat prescribing record which can be supplemented with information given by the patient and/or carer.

- Checking this information against the drug chart in hospital and ensuring that any discrepancies that appear are investigated and accounted for, and any unintended discrepancies are acted upon
- Documenting appropriately any omissions changes and discrepancies.

A variety of medication reconciliation definitions are known internationally (Table 1).

Table 1 Definitions of medication reconciliation

Name	Definition	Country/Organisation	Cited by: -
Medication reconciliation	• Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking — including drug name, dosage, frequency, and route — and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital.	Institute for Healthcare Improvement (IHI) Institute for Healthcare Improvement (IHI). USA	http://www.ihi.org/IHI/Topics/Patie ntSafety/MedicationSystems/
Medication reconciliation	 Medication reconciliation is a formal process for creating the most complete and accurate list possible of all pre-admission medications for each patient and comparing the physician's admission, transfer, and/or discharge orders against that list. Discrepancies are brought to the attention of the physician and if appropriate, changes are made to the orders. Any resulting changes in orders are documented. 		Rogers et al 2006
Medication reconciliation	 Creating the most complete and accurate list possible or "Best Possible Medication History" (BPMH) of all medications the patient is currently taking—also called the "home" medication list Comparing the list against the admission, transfer, and/or discharge orders when writing medication orders; identifying and bringing any discrepancies to the attention of the prescribing health professional; and, if appropriate, making changes to the orders while ensuring the changes are documented. 		Assuring Medication Accuracy at Transitions in Care. Patient Safety Solutions 2007, volume 1, solution 6 May 2007. World Health Organisation.
	 Updating the list as new orders are written to reflect all of the patient's current medications. 		
	 Communicating the list to the next provider of care whenever the patient is transferred or discharged and providing the list to the patient at the time of discharge. 		

Chapter 1

Introduction

Name	Definition	Country/Organisation	Cited by: -
Medicines reconciliation* (UK term used for medication reconciliation)	 Collecting information on the pre-admission medication history using the most recent and accurate sources of information to create a full and current list of medicines (for example, GP repeat prescribing record supplemented by information from the patient and/or carer), Checking or verifying this list against the current prescription chart in the hospital, ensuring any discrepancies are accounted for and action is taken appropriately Communicating through appropriate documentation, any changes, omissions and discrepancies. 	National Prescribing Centre	National Institute for Health and Clinical Excellence. National Patient Safety Agency. PSG001. Technical patient safety solutions for medicines reconciliation on admission of adults to hospital. London: NICE; 2007.

1.2.2 Role and healthcare professional involvement in reconciling medication

The WHO suggested that there should be "clear assignment of roles and responsibilities for all steps in the medication reconciliation process to qualified individuals, within a context of shared accountability." This includes the provider of primary care, physicians, nurses, pharmacists and other clinicians.

In the USA, the patient initiative developed and implemented by the Massachusetts Coalition for the prevention of Medical Errors and the Massachusetts Hospital Association had a process of safe practice recommendations for reconciling medications at admission (Rogers et al. 2006). The process included use of a standardised reconciliation form that doubled up as an order form, with healthcare professionals sharing responsibilities in each stage of the process. The guidance emphasised that a nurse, mid-level provider or physician should take a thorough medication history as possible.

In England, current practice of taking a medication history and prescribing on admission is typically undertaken by junior doctors. In some units, pharmacist are involved in reconciling the medicines shortly after admission, though there is recognition that pharmacists may not be available out of hours (NICE 2007).

In the US, histories may be taken by nurses, physicians or pharmacists upon admission. After this initial medication history is taken, the physician writes up the admission orders (Roger 2006). The time frame taken for the pre-admission and admission medications to be reconciled is normally within 24 hours (Rogers et al, 2006) and also 24 hours by the pharmacist in England (NPC accessed online at 2010).

1.2.3 Definitions of transitions in care medication discrepancies

'Medication discrepancies' is a common term used in studies of differences of medications between one interface of care and another, for example when a patient is admitted, transferred or discharged from hospital. There are many variations in its definition and classification.

Medication error is also used to describe discrepancies that have occurred, however, this can only truly be applied to the discrepancies that have occurred as a result of an unintended variation in comparison to the previous pre-admission medication.

The word 'discrepancy' is defined in the Oxford compact dictionary as difference; inconsistency and based on the Latin term *discrepare* 'to be discordant' (Oxford University Press, 1996).

The reason origin and exact time at which the term medication discrepancy was coined is unclear, and very few studies except one explained in detail why this term was used rather than simply medication error. Coleman et al (2005), used medication discrepancy to describe differences between the a patient's discharge letter and post discharge medication list because there was no single medication list of what a patient should be taking, a so called 'Gold Standard'. If there was such a 'Gold Standard' medication list, then

any variation of medication record from this standard could be defined as a mediation error. However Coleman et al commented that for patients receiving medications from multiple prescribers across different settings, such a medication list did not exist. Hence, the term discrepancy, which implied that there was a lack of agreement between different medication regimens was considered a more precise term for capturing medication errors that could occur during transitions across care settings (Coleman et al 2005).

The definition of discrepancy can also vary depending on the transition of care point for the patient, for example at admission, discharge or post discharge.

Medication discrepancy definition used at admission

A prospective observational study of hospitalised adult patients in Canada, by Cornish and colleagues defined the term medication discrepancy as any difference between the medication use history (which was obtained by a pharmacist/pharmacy student/medical doctor using various sources of information) and the admission medication orders. The study also distinguished the discrepancies as either intentional (intended) or unintentional (unintended). Unintended discrepancies were the primary outcome measured and clinically assessed for potential patient harm if the discrepancy had not been rectified for a week (Cornish et al 2005).

Chapter 1

Medication discrepancy definition used at discharge

Observational studies reporting discrepancies occurring at the point of hospital discharge usually defined a discrepancy by comparing the medications prescribed on the discharge list against a 'best possible medication discharge list' BPMDL. An assessment team defined a best possible discharge medication discharge list and would compare the initial written discharge letters against this. Discrepancies were classified as either intentional or unintentional and this was clarified by referring to the physician who wrote the discharge summary. The unintentional discrepancies were further classified into actual or potential unintentional discrepancies (Wong et al 2008).

In a study conducted in Ireland, discrepancies were identified by checking if there were any discrepancies that occurred anywhere along the patient's entire hospital stay from admission to the point of discharge (Grimes et al 2010).

Medication discrepancy definitions used post hospital discharge

The methodology of existing studies that were designed to observe medication errors or discrepancies that occurred after a patient was discharged from hospital varied. The variations that occurred were in relation to the definition used to describe the medication discrepancy, and the patient follow up date.

A study of older adults in the USA post hospital discharge defined a post discharge discrepancy as a difference between the medications prescribed by the hospital at discharge against the reported list of medications at a discharge follow up by a nurse within 24-72 hours after hospital discharge. The study had used a Medication Discrepancy Tool (MDT see figure 1) and involved the patient/carer to help establish the types of discrepancies that occurred (Coleman et al 2006). The authors explained that hospital physicians may not have known the complete list of long term medications, and that any variances which may result from this may not be an actual medication error. Hence the word discrepancy was used.

Figure 1 – Medication Discrepancy Tool (from Smith et al 2004)

DT is designed to facilitate reconciliation of medi	cation regimen across settings and prescribers			
Medication Discrepancy Event Description: Complete one form for each discrepancy				
auses and Contributing Factors :: Check all that	apply			
-	gests patient's perspective and/or intended meaning			
Patient Level				
Adverse Drug Reaction or side effects	Intentional non-adherence			
Intolerance	"I was told to take this but I choose not to.			
Didn't fill prescription	Non-intentional non-adherence (ie:Knowledge de			
Didn't need prescription	"I don't understand how to take this medication."			
Money/financial barriers	Performance deficit			
	"Maybe someone showed me, but I can't			
Contract land	demonstrate to you that I can."			
System Level Prescribed with known allergies/intolerances	Duplication.			
Conflicting information from different informational sources.				
	Incorrect dosage			
For example, discharge instructions indicate				
For example, discharge instructions indicate one thing and pill bottle says another.	Incorrect quantity			
	Incorrect quantity Incorrect label			
one thing and pill bottle says another.	Incorrect label			
one thing and pill bottle says another. Confusion between brand & generic names	Incorrect label			

✓ Resolution :: check all that apply

Advised to stop taking/start taking/change administration of medications

- Discussed potential benefits and harm that may result from non-adherence
- Encouraged patient to call PCP/specialist about problem
- Encouraged patient to schedule an appointment with PCP/specialist to discuss problem at next visit
- Encouraged patient to talk to pharmacist about problem
- Addressed performance/knowledge deficit
- Provided resource information to facilitate adherence
- Other _____

In the UK a retrospective service evaluation used a validated tool by Dean et al (2000) to define discrepancies that occur after a patient has been discharged from hospital as medication errors (Alldred et al 2000). Dean et al used a consensus method to define and validate situations and scenarios that would be considered as medication error. The results of this Delphi process categorised the scenarios into the following: - situations that should be included as prescribing errors which was categorised further into errors in decision making and errors in prescription writing; scenarios that may be considered as prescribing errors depending on the individual clinical situation; and situations that should be excluded as prescribing errors. (Dean et al 2000). The conference abstract from Alldred et al did not state if the validated tool was adapted prior to the use on defining post discharge discrepancies and did not specifically define how the discrepancies were categorised. Alldred et al reported that the discrepancies were classified as intentional and unintentional and that the hospital was contacted to confirm this. The abstract did report that the most common error was omission from either the discharge prescription or repeat prescription.

1.3 Medication reconciliation specific publications, methodology and results in adults

Medication discrepancies and errors that occur across transitions in hospital care have become important issues affecting hospitalised adults. This section discusses the key papers that report on medication discrepancies/medication errors in adult and its methodology.

1.3.1 A discussion on the review conducted in adults - NICE Commissioned Medication reconciliation systematic review by Campbell et al 2007

A systematic review by Campbell et al (2007) examined interventions that addressed the problem of a medication error occurring at admission to hospital from a community setting. The review also sought to calculate the cost effectiveness of medication reconciliation. The paediatric population was excluded from the review on the basis that there were differences in service provision to children and also the additional risk factors children presented for medication error and associated harm.

They used a range of electronic databases for studies that were published in English that reported on medication reconciliation interventions that sought to improve the transfer of accurate information about medicine use by patient in the community to prevent inaccuracies of medication prescriptions upon hospital admission (Campbell et al 2007). The databases that were used included Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Database of Systematic reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Embase, Medline, Medline InProcess and Other Non-indexed Citations, NHS Database of Abstracts of Reviews of Effects (DARE), Science Citation Index (SCI) and Social Sciences Citation Index (SSCI). The database International Pharmaceutical Abstracts was not included in their search strategy despite the attempts made to identify 'grey' literature. The appendices of the report provided an example of key words that were used in one particular electronic database (Medline), and the search terms that were used were based on medication reconciliation terms for example "medication reconciliation", "medication history", "discharge document" and also terms based on the interfaces of transitions in care for example patient admission or patient discharge or patient transfer (Campbell et al 2007).

They found 16 studies out of 3111 references, of which one was a randomised control trial of a study which compared pharmacists and nurseconducted medication reconciliation in a pre-admission surgical unit in the USA. This was published as a conference abstract at the time of the review (Kwan et al 2005).

The review was aimed at estimating the clinical and cost effectiveness of interventions aimed at the prevention of medication error at the point of admission. The literature review was not aimed at identifying studies observing the incidence of 'medication errors' in adults, before finding interventions and also excluded paediatric patients under the age of 16 (Campbell et al 2007).

1.3.2 Reported incidences and rates of medication discrepancies in observational studies upon hospital admission, discharge and post discharge in adults

This section summarises studies that have sought to establish the occurrence and incidences of medication discrepancies that occurred during transitions in care in adults.

The most commonly cited study in medication reconciliation is Cornish et al at (2005) examining the potential clinical significance of unintended discrepancies that occurred on hospital admission. This was a prospective observational study conducted over three months in 2003, of consecutive patients who were admitted to hospital with more than 4 chronic medications (Cornish et al 2005). Their medication use history was established by the study team comprising of a pharmacy student or medical student. Α thorough history was obtained patient or caregiver interviews, inspection of the prescription vials (medication bottles) and follow up with a community pharmacy. They defined a discrepancy as the difference between the medication use history and the admission medication orders. Over the study period, 523 patients were admitted of which 151 met the inclusion criteria. Eighty one patients (53%) had at least one unintended discrepancy. Out of the 140 unintentional discrepancies, Cornish reported that 32.9% were judged to have potential to cause moderate harm and 5.7% were judged to cause severe harm (Cornish et al 2005).

In terms of medication reconciliation at the point of hospital discharge, a study from reviewing discharges from two Irish hospitals over a 2 years 5

month period reported that there were discrepancies in 50% of 1245 patient episodes representing 16% of 9569 medication orders. Of the discrepancies 2% were classified as severe, 63% were moderate and 35% was minor. (Grimes et al 2010).

A US prospective 24-72 hour post hospital discharge follow up study of older patients aged 65, identified 53 (14.1%) out of 375 patients experiencing one or more medication discrepancies (Coleman et al 2005). Although the causes and contributory factors of the discrepancies were identified and a suggested solution was provided for the patient, the potential clinical harm or significance of these discrepancies were not assessed. Hence from the post discharge study, the incidence and causes of post discharge discrepancies were identified, however there is no evidence to show that patients who experienced these discrepancies are at a risk of harm as a result of the discrepancies identified.

1.3.3 Summary

From the previous sections, it can be seen that there were many variations in definitions for the terms of medication reconciliation, the intervention which aims to prevent potential adverse reactions as a result of variations of medication regimens across the interfaces of care. Studies which have explored the rate of medication discrepancies have shown that the definition of what a discrepancy is also varies, causing homogeneity in the study design. A review conducted by NICE has reviewed studies of medication reconciliation interventions, which has included the use of grey literature and

conference abstracts, however the electronic database of International pharmaceutical abstracts was not used as part of their search strategy. Published studies of outcomes of selected studies on adults have shown that discrepancies occur at each interface of care and in the population of older adults in general. These discrepancies identified were classed having potential for causing adverse clinical consequences if unresolved.

In the next section, the differences between paediatric and adult services are discussed, compared and contrast to establish whether the adult evidence and guidance model for Medication reconciliation in the UK can be applied to children or whether there is a knowledge gap on whether medication reconciliation should be conducted in children.

1.4 The difference between paediatric and adult health services and medicines use studies conducted in children

The national guidance for medication reconciliation in adults admitted to hospitals in England excluded children. The reason given for the exclusion of children from the guidance was because of the heterogeneity between adult and paediatric services (Campbell et al 2007). The guidance covered patients between the ages of 16 – 18 years of age; however some patients would receive hospital treatment and be users of paediatric services. From this the evidence for medication reconciliation in children was not included in the systematic literature review search that was commissioned by NICE to find evidence on the clinical effectiveness and cost effectiveness of medication reconciliation (Campbell et al 2007). Hence, there were

knowledge gaps on whether medication reconciliation was clinically effective or required in children.

One question that would be raised is whether any medication reconciliation intervention designs, principals and policies in adults can be applied directly to children. NICE did not gather any paediatric data and specified that the guidance applied to adults aged 16 years and above (NICE 2007), and the authors of the review commissioned had noted the differences between adults and children services (Campbell et al 2007). The NHS national service framework for children and young people set by the Department of Health (DH) in 2007 have defined some minimum standards of delivery for a hospital service fit for children in the twenty first century and aims to make hospital a more child-friendly experience (Department of Health 2007). For any medication reconciliation service, an approach would need to be childfriendly. A report by the Child Health and Maternity Partnership looking at the fundamentals of commissioning health services for children reported that GPs and other primary care staff may not have the competencies, confidence or capacity to manage the needs of children and young people effectively. Furthermore, some hospitals offer an open access approach to the management of long term conditions and paediatricians provided direct access to advice to parents and so bypassing the primary care physician (Child Health and Maternity Partnership 2011). The report concluded that primary and community care services for children and young people need to be able to refer to more specialist support if they are not confident to manage the child themselves. These reports from the National Service Framework

(NSF) and Child Health and Maternity Partnership (CHaMP) suggest that children's services differ from adults and that a different approach may be required.

1.4.1 What is the difference between children's health services and adults?

In 2006 the Department of Health Report: "Transition: getting it right for young people" stated that transitions from children's to adult health services had become an important issue for several reasons. One particular reason was that children have been surviving into adult life with conditions that were previously lethal in early childhood. Many of these conditions may be unfamiliar to those working in adult practices. In paediatric care, the medical and surgical specialists and general paediatricians played an important role in co-ordinating care and taking a holistic view of their needs and including that of their family. When an adolescent patient reached the age of an adult it was difficult to identify anyone to take up that role after transitions to adult service (Department of Health 2006). The report stated that transitions models for moving paediatric patients from paediatric to adult health care varied depending upon the condition gave some examples of long term conditions such as congenital heart disease and diabetes (Department of Health 2006).

When an adolescent is transferred from paediatric to adult services, it has been reported that patients and their families are reluctant to leave the paediatric team (McDonagh 2005; Shaw et al 2004). Patients who have been transferred from paediatric to adult services felt that the levels of expertise, empathy and resources were lower in adult services compared with those received in paediatric services (Shaw et al 2004).

Another obvious difference between paediatric and adult healthcare services is that with children and adolescents, parents or carers are involved in the care of the patient. The age at which the 'child' takes over managing their medication varies. A report from the Royal Colleges of Physicians in Edinburgh found that during transition from paediatric to adult services, some parents find it difficult to let go and enable their children to manage their care independently (Royal College of Physicians of Edinburgh 2008).

1.4.2 Previous paediatric studies and prescribing error. Has medication reconciliation been part of previous studies?

There are many reviews and studies on medication errors and medicines use in children. The purpose of this section is to review a selection of studies and systematic reviews to identify if these included observations of medication errors caused as a result of transitions of care providers as part of the outcome measures, and/or if the results reported reasons related to "transitions of care" as a cause of the error.

Systematic reviews examining the incidence and nature of dosing errors, and medication errors in paediatric studies have found that the most common

errors were dosing errors often involving ten times the actual dose required as a result of miscalculation. Other reasons behind the errors were reported as wrong drug, wrong route of administration, wrong transcription or documentation, incorrect or missing date, wrong frequency of administration, and omission errors. The review did not report if these medication errors were a result of a discrepancy between a patient's pre-admission medication list and current medication order (Wong et al 2004, Ghaleb et al 2006a).

A study identifying prescribing errors on drug charts and preparation and administration errors of nurses on paediatric wards revealed that the most common type of medication error was incomplete prescriptions which included the route of administration and the dose intended by the prescriber. Details of the exact cause and reasons behind the prescriptions being incomplete were not discussed or explored further (Ghaleb et al 2006b).

Studies have also been conducted to evaluate the impact of introducing electronic prescribing to the inpatient hospital setting and on the prescribing on hospital outpatient prescriptions at a tertiary children's hospital in London. The focus of the study covered the impact of the intervention and reduction of prescribing errors going from handwritten prescriptions to electronic prescriptions; however the objectives and findings of the study were not directed and specified to establish whether transition in care contributed to errors (Jani et al 2008;2010).

An interview study of children discharged from hospital with an unlicensed medicine reported that 33% of parents had problems with

obtaining medicines in particular. This study did not observe or report on discrepancies in prescribing of medication and doses that may have occurred (Wong et al 2009b).

From a brief selective review of existing studies and literature reviews regarding medication errors in children, it was found that neither the methods nor the results for the studies had specifically reported medication errors in relation to a discrepancy occurring during transitions in care. Prior to conducting research into medication reconciliation in children and in order to be sure that studies related to medication errors or discrepancies occurring across the interfaces of care specifically in the paediatric setting, a systematic review of the literature was deemed necessary.

1.5 Literature review on the epidemiology of medication discrepancies upon hospital admission, transfer and discharge in children

Note: - This literature review was initially conducted in November 2010, and subsequently updated

The aim of this literature review was to explore the occurrence and rate of medication discrepancies in children up to 18 years of age.

Primary objective: - to review original studies reporting medication discrepancies at transitions to and from the hospital setting in the paediatric population to identify the rate and clinical significance of the discrepancies

Secondary objective: - to ascertain if any specific interventions have been used for medication reconciliation in paediatric settings.

1.5.1 Methods

A search of the literature was carried out on 7th May 2012 using the following electronic bibliographic databases - PubMed, OVID Embase (1980 to 2012 Week 18), ISI web of Science, ISI Biosis, Cumulative Index to Nursing and Allied Health Literature, and OVID International Pharmaceutical Abstracts (1970 to April 2012). Endnotes® was used to store and sort the citations. No limits were imposed on any of the databases to increase the sensitivity of the search and capture all possible studies in relation to paediatrics.

Search Strategy

The search strategy was developed following discussion between the authors and was based on the systematic review of medication reconciliation in adults by NICE. (NICE/NPSA 2007) The key words used were: -["Medicine discrepancy" or "medication discrepancy" or "drug discrepancy" or "medicine discrepancies" or "medication discrepancies" or "drug discrepancies" or "medication difference" or "difference in medication" or "medicine disparity" or "medication disparity" or "drug disparity" or "medicine disparities" or "medication disparities" or "drug disparities" or "medicine omission" or "drug omission" or "medicine omission" or "medication omissions" or "drug omissions" or "drug difference" or "drug differences" or "medication difference" or "difference in medication" or "medication history" or "medicines reconciliation" or "medication reconciliation" or "drug history"] and ["hospital admission" or "hospital re-admission" or "hospital transfer" or "hospital discharge" or "admitted to hospital" or admission to hospital" or

"medication error"]. The same keywords were used in all databases to ensure consistency.

Study selection

Titles and abstracts were initially screened by two independent reviewers (CH screened all the titles and abstracts and, YJ, DT, ST, AS, IW, KW did the second screening on a proportion of the abstracts distributed equally) using a checklist and potentially relevant articles selected for further review and data extraction. Discrepancies between the reviewers were resolved through full text review of the article, followed by discussion and further correspondence until agreement was reached. For the potentially relevant papers, the full text articles were reviewed independently by CH and YJ for eligibility and data extraction.

The reviewers used a common set of criteria to review and screen the articles, (see Figure 2). Papers were selected using the following criteria:

The titles and abstracts were initially reviewed to see if each article was reporting a study related to medication reconciliation or discrepancies of medication upon hospital admission, discharge or transferred. The remainders were screened to see if it contained information on discrepancies or mention a medication reconciliation service, followed by whether the abstract indicated a paediatric population. After the initial review, 484 articles were identified as relevant, the full text articles were screened. 45 articles did not have full text in English and these were excluded. Out of the 439 articles remaining, 20 were identified for data extraction. An additional

article was identified through the reference list of an extracted relevant article and eventually 10 studies were included for review.

Excluded studies characteristics

Studies that were potentially relevant up to the point of consideration for data extraction were excluded if the results contained mixed paediatric and adult data that had not been stratified, stated ages of late adolescent patients seen in non-paediatric settings, were not original research, and did not clearly define discrepancies or intervention.

Data collection process (Data extraction)

An excel spreadsheet based on the Cochrane Handbook of systematic review of intervention checklist was developed (Higgins and Green 2011). Two reviewers (CH and YJ) used the spreadsheet to extract the data from the included studies and these two spreadsheets were compared. Any disagreements were resolved via discussion between the two reviewers and a final data table was generated.

Five authors were contacted for further information. All responded, however only 2 provided additional information on sample size and 3 provided information that there were no fully published studies for the grey literature identified.

For studies with multiple publications, only the most recent article with full information was included. Thus for data in conference abstracts which were subsequently published as a full article, provided that the reviewers agreed that the data were repeated, only information from the full article was reviewed.

Data Items

Information was extracted from each included paper on: 1) characteristics of the participants (including age, gender, setting, country; transition of care) 2) characteristics of the methods (including criteria used to define the discrepancy; study design; duration; recruitment and selection; inclusion and exclusion criteria used; methods of allocation and comparison groups if an intervention was reported) 3) use of any medication reconciliation interventions and 4) type of outcome measure (including number of discrepancy, for example, the type of pre-admission medication list versus the type of admission medication order used; clinical assessment for actual or potential harm; tools and scale used (if reported) to assess harm).

Summary measures (for intended outcomes)

The primary outcome measures were either the incidence or occurrence of discrepancies in a sample of paediatric patients expressed as a number of unintended discrepancies per patient, and the types of discrepancy. The secondary measure was the capture and identification of specific interventions used for conducting medication reconciliation in hospitalized children.

Analysis

The eligible studies did not consist of randomized controlled trials and were of a heterogeneous nature with differences in definition of "best possible medication history", transition point of study and denominator used. Hence the results could not undergo a meta-analysis.

1.5.2 Results

The search strategy produced 1501 results, after removal of duplicates; 45 articles were excluded as the full text was not in English. After full text review, 439 articles were highlighted as potentially relevant and after a full text review, this was narrowed down to 20. One additional article was found on the reference list of a relevant article and hence 21 articles were considered for data extraction. After data extraction 10 studies met the inclusion criteria (See figure 2). Summaries of the 11 studies that met the inclusion criteria but were later excluded are provided in table 2 with the reasons for exclusion (Agrawal et al 2007; Agrawal & Wu 2009; Bedard et al 2009; Carter et al 2006; Coffey et al 2009a; Collins et al 2004; Kwan et al 2007; Miller et al 2008; Rothschild et al 2010; Weingart et al 2007; White et al 2011; Wong et al 2008).

Figure 2 – Search Procedure and detailed criteria used to select the papers

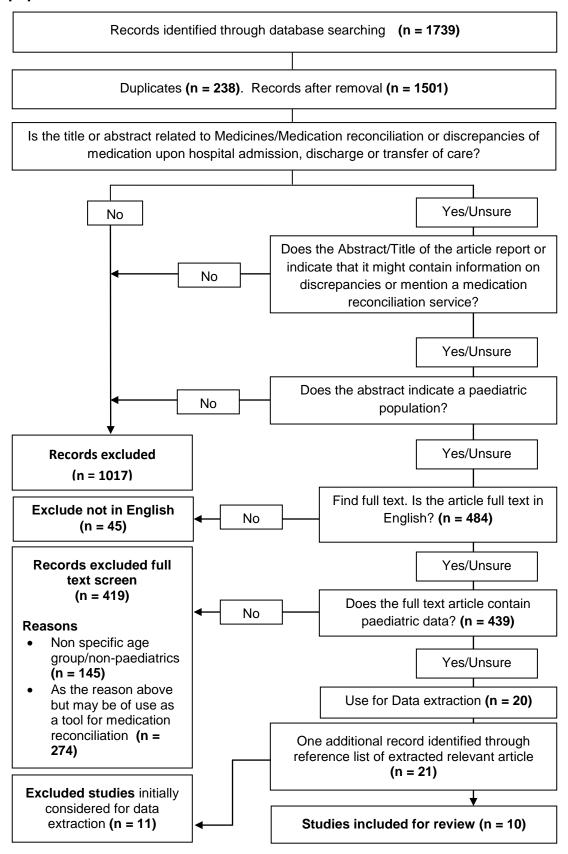


Table 2 Details of studies excluded during the data extraction stage of the literature review

Author name	Summary of study (Purpose, design, findings)	Reason for Exclusion
Agrawal et al 2007 (Pilot) ; Agrawal et al 2009 (full)	Primary objective was to evaluate a medication reconciliation computerized recording system and its impact on reducing medication discrepancies upon implementation.	Study design was not paediatrics and it was events that were used as opposed to discrepancies
Bedard et al 2011	Quality of the admission medication orders of on the drug chart against the medication history taken was measured.	The quality of the source of medicine used to establish the medication history was measured as opposed to identifying discrepancies upon hospital admission
Carter et al 2006	The purpose of the study was to assess the quality of medication history taking of a pharmacist compared with other professions.	Paediatric results could not be separated from the adults.
Coffey et al 2009a	Describes 1.5 discrepancies found per patient on average in the paediatric setting. (Canadian Study)	Commentary; not original research paper
Collins et al 2004	A paper on the accuracy of medication histories (including allergy status) by the physician as well as the accuracy of General Practitioner records.	This paper included patients 16 years of age and over, however data for 16-18 year old patients could not be extracted.
Kwan et al 2007	Randomized interventional study comparing standard care (nurses taking medication history, surgeon generated postoperative medication order form) with an intervention (structured pharmacist medication history interview with assessment and generation of a postoperative medication order form) in a surgical preadmission clinic. The primary endpoint was the number of patients with at least one postoperative medication discrepancy related to home medication.	Patients were 18+ years old in the intervention arm and in the standard care the youngest patient was 16; data for 16-18 year old patients could not be extracted.
Miller et al 2008	Comparison of medication reconciliation by a pharmacist at a trauma unit with medication reconciliation done by the clinician and nurse. The main finding was that clinician's medication reconciliation was commonly incomplete and inaccurate. However, full reconciliation by the pharmacist was extremely costly in terms of time delay (mean 3 days) and effort, and could not be accomplished promptly in the emergency department.	Study was excluded as the patients were mainly adult patients with some patients within the age range of 15 - 35 years. Data for paediatric patients could not be extracted.

Author name	Summary of study (Purpose, design, findings)	Reason for Exclusion
Rothschild et al 2010	Four site study on the impact of having a Pharmacist working in the emergency department on reducing adverse drug events.	The data for the age group of interested could not be extracted.
Weingart et al 2007	The purpose of the study was to assess a medication reconciliation program that was developed as a patient-clinician partnership intervention. Baseline levels of medication errors and omissions and how many were updated using medication reconciliation. This was conducted in an ambulatory oncology setting.	The data for the age group of interested could not be extracted.
White et al 2011	Report of improvement methods and reliability principles to develop and implement a process for medication reconciliation completion.	The study focus was on process methods, quality improvement as opposed to measuring the occurrence of discrepancies.
Wong JD et al 2008	Prospective study on consecutively admitted patients to a general internal medicine ward. Unintentional discrepancies that occur on hospital discharge were recorded. The discrepancies were assessed through comparison of a best possible medication discharge list with the actual discharge prescriptions.	The data for the age group of interested could not be extracted.

Study characteristics

Ten paediatric studies were identified from the literature search, of which 7 were full publications (Coffey et al 2009b; Coffey et al 2009c; Dersch-Mills et al; Gardner and Graner 2009; Marconi et al 2012; Stone et al 2010; Terry et al 2010) and 3 were conference abstracts (Caligiuri et al 2009; Lasak-Temme et al 2008; Ling et al 2009). Key characteristics of the studies are described in the sections below, and detailed in table 3 and 4.

Introduction

Table 3 Characteristics of studies included in the literature view

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?											
Caligiuri et al 2009 Winnipeg, Canada	One Site. Length of study: NR	Inclusion Patients transferred from ICU	Transfer	Pre- assessment: NR. 100 Patients in	NR	Unintentional discrepancies (ICU versus transfer orders at baseline)	Per patient	Medication transfer orders	NR											
(Conference			the study. 60 pre-; 20 early phase; 20 full implementation	60 pre-; 20 early phase;	60 pre-; 20 early phase	60 p 20 e	60 pre-; 20 early pł	60 pre-; 20 early phase;	60 pre-; 20 early phase;	60 pre-; 20 early phase;	60 pre-; 20 early phase;	60 pre-; 20 early phase;	60 pre-; 20 early phase;	60 pre-; 20 early phase;	60 pre-; 20 early phase;		Pre- implementation of MR process	0.53	16.40%	
Abstract)						Early post implementation of MR process	0.1	3.30%												
						Full MR process implementation	0.05	0.60%												
Coffey et al 2009b Toronto, Canada	Two sites. (1 adult 1 paediatric). 27 Months (Hospital for Sick Kids)	Inclusion Patients on four or more prescription medications high alert medication unclear history	Admission	NR	NR	Unintentional discrepancies	1.5 per patient	not stated	NR											

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?
Coffey et al 2009c	One Site. 10 weeks	Inclusion All admissions to	issions to p d general 2 rics unit on s ged	356 patient's pre-assessed.	Number of meds not stated. Median 4 medicines per patient, range 0-15	At least one discrepancy	206 patients	76% of patients	Yes (potential to cause
Toronto, Canada		a 60 bed general paediatrics unit <i>Exclusion</i> patients		272 included		At least one (range 0-9) unintentional discrepancies	59 patients	22% of patients	discomfort or deterioration using 3 physicians to rate) • Low • Moderate • Severe
		discharged before 24 hours				Low	NR	71%	
		before 24 hours				Moderate	NR	23%	
						Severe	NR	6%	
Dersch-Mills et al 2011 Calgary, Canada.	1 site - 2 months	Inclusion Patients under 18 years of age. Exclusion Patients already been admitted for more than 48 hours at the time at which they were identified as eligible, or if they were transferred from another ward.	Admission – the first 24 hours	Pre- assessment: NR. 99 patients in total.	NR	Discrepancy score stated as completeness score of admission history	NR	NR	N/A

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?
Gardner et al 2009 Minnesota USA.	One site - 16 months	NR	Admission and transfer	Pre- assessment: NR. 85% admission	NR	MR related interventions	567	100%	Yes – Patient impact. • Minimal (27%),
				and 100% transfers.	ĺ	Admission	522	92%	 Moderate (66%) Severe
						Transfer	46	8%	(7%)
						Omissions	339	65%	-
						Subtherapeutic dose	78	15%	
						Supratherapeutic dose	68	13%	-
						Incorrect medication	27	5%	-
						No longer taking	10	2%	-

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?
Lasak Temme et al 2008 California, USA.	One site. One month.	Inclusion: paediatric patients (less than or equal to 21 years of age) admitted to the UCSF Children's hospital between September 1 2007 - September 30 2007 for more than 24 hours. <i>Exclusion:</i> patients without both pharmacist and physician generated medication lists. Electronic medical charts were reviewed.	Admission	Number included in the study = 253 patients.	NR	Medication reconciliation Discrepancy	719	Cannot calculate	NR

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?
Ling et al 2009 Winnipeg, Canada.	One site 4 weeks	Inclusion Patients being discharged	Discharge	Pre-assessment - not stated. 28 Patients.	111 Medicines in total.	At least one discrepancy	12 patients; 17 medicines	43% patients; 15% medicines	NR
(Conference abstract)		between a 4 week period on the paediatric medication ward in July 2008. (Retrospective chart review)			Average of 4 per patient	Number of medication discrepancies classified as "Unchanged pre- admission medications"	9 out of 17 discrepancies in total	53%	
Marconi et al 2012 Los Angeles, USA.	One site Length of study NR	Inclusion All patients admission during the the pre- implementation	Admission	1164 (396 charts reviewed in April 2007, 363 reviewed in April 2009 and 405 reviewed in	NR	Missed non urgent medications (pre implementation in April 2007)	125	71% (of 396 charts reviewed)	NR
		month, implementation month and 6 month post- implementation month charts		October 2009)		Missed "non urgent medications (April 2009)	62	38.3% (of 363 charts reviewed)	
		reviewed.				Missed non urgent medications (October 2009)	43	31.8% (of 405 charts reviewed)	

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?
Stone et al 2010 Utah, USA.	One site. 3 weeks.	Inclusion Paediatric admissions with medically	Admission	219 admissions 32 eligible 28 evaluated. 23 In the study.	217 in total. 182 reconciled. Average 9.4	Admission order errors	39	21.4% of admitting order medications	Yes (potential risk using a consensus method)
		complex conditions			medicines per patient	Omissions	17	43.6% of errors	• Not
		Exclusion: Patients with no medicines on admission				Dosage	12	30.80%	significant 15; • Significant 15;
						Formulation	2	5%	 Serious 1; Life
						Frequency	8	20.50%	threatening 5;
						No route	0	0	• Fatal 0.
						Patients	13	56.5% of patients	-
						Number of errors which could have been potential ADEs	21 out of 39	54%	

Author name, year, and City/Country of Study.	Number of site(s) and Length of study	Inclusion/ Exclusion criteria	Point of transition (Admission transfer or Discharge?)	Number of patients pre- assessed and number in the study	Number of Medicines (total) and average number of medicines per patient	Type of discrepancy	Number of medication discrepancies	% of discrepancies	Any scales used for errors?
Terry et al 2010 Birmingham, UK.	One site. 6 months.	Inclusion Neurosurgical ward admissions. 100 Consecutive patients on the neurosurgical		pre-assessed. 100 patients in	e-assessed. 00 patients in udy	(PAM VS AMO) differences	45 (out of 97 PAM orders)	46% orders	Yes panel assessment of effect on patient discomfort or clinical deterioration • Class 1 = unlikely 19, 50% • Class 2 = potential to cause moderate 11, 29% • Class 3 = potential to
		ward. <i>Exclusions</i> : caregiver not				(PAM VS AMO) discrepancies	38 (out of 97 PAM orders)	39%	
		available for interview; medication information not accessible; medication reconciliation				(PAM VS POD) differences (59 PODs in total)	15 orders (11 unlabelled, 3 wrong dose)	25%	
		could not be completed for practical reasons e.g. Weekends.				CAREGIVER VS PAM differences (97 PAM orders)	43 (out of 97 PAM orders)	44%	results in severe 8, 21%

Table 4 Details of studies reporting a medication reconciliation intervention

	Studies reporting a medication reconciliation intervention with details of comparative results (if available)
Caligiuri 2009 (Conference Abstract)	 Pharmacy computer system (Cerner) to generate a complete and accurate medication reconciliation form to serve as a transfer order. Discrepancies reported on a per patient basis only. Baseline discrepancy = 0.53 unintentional discrepancies per patient Early implementation = 0.10 unintentional discrepancies per patient Full implementation = 0.05 unintentional discrepancies per patient
Coffey et al 2009	Best possible medication history form. The doctors were expected to use this form. Reconciliation was conducted by the nurse, and only in cases where the medications for the patient was 4 or more did the reconciliation was carried out by a pharmacist (due to resources). This intervention was monitored by physician compliance of the use of the form.
Coffey et al 2009	Not an intervention but a student pharmacist conducted a best possible medication history during the study to use to compare against the initial admission orders to identify discrepancies.
Dersch-Mills et al 2011	 Best possible medication history by: - (1) Reviewing the physician's admission history and the medication list in the patient's chart (2) Reviewing the preceding 6 months of prescription activity as recorded in a provincial prescription database (3) Contact with the patient's community pharmacist if the patient used the same pharmacy regularly (4) Review of other resources on a patient specific basis e.g. medication admission records from previous admissions to hospital or prescription vials) (5) Interview of the caregiver about medications being taken at home
Gardner et al 2009	Intervention was carried out by a pharmacist, but the types of interventions were not fully described except for happening upon admission, transfer. Also the pharmacists intervene by taking an independent medication history and verify or update the patient provided medication list. A computerized module was developed.
Lasak-Temme et al 2008 (Conference Abstract)	Pharmacist obtained medication history. Components include: - current/recently discontinued medications (including prescription and non-prescription medications, dietary supplements and herbal products), mother's medication history for breast-fed children and allergy history.

	Studies reporting a medication reconciliation intervention with details of comparative results (if available)
Ling et al 2009 (Conference Abstract)	The Best Possible Medication Discharge Plan was determined for each patient by reviewing the admission medication reconciliation information, inpatient orders, pharmacy profile, administration records and discharge prescriptions.
Marconi et al 2012	Number of patients approached 422 pre-implementation, 386 during month one of pharmacist implementation, 417 admissions 6 months post implementation Number of patients allocated in the pre-implementation group 396 reviewed Number of patients allocated in the post-implementation group 363 reviewed during the month of the launch of the emergency department pharmacist; 405 reviewed - 6 months post implementation Reported effect and outcome with confidence intervals (or P values)
Stone et al 2010	Medication reconciliation for admission using 5 sources of information. This was not a comparative study but did look at the discrepancies that were being picked up by conducting medication reconciliation.
Terry et al 2010	 Medication reconciliation by a senior clinical pharmacist which included four stages: (1) Determining the pre-admission medication list (2) Examination of the patient's own drugs brought in on admission (3) Identification of most recent medication regimens described as administered or supervised by caregiver(s) prior to admission (4) Initial admission medication orders prescribed on admission to the neurosurgical ward

Participants and setting

All studies with the exception of one were conducted exclusively in paediatric care settings; one study reported medication reconciliation events in both adult and paediatric settings. Two studies (Terry et al 2010; Ling et al 2009) reported the age range of the patients, but none specified the gender. Six studies (Coffey et al 2009b; Coffey et al 2009c; Dersch-Mills et al 2011; Stone et al 2010; Terry et al 2010; Lasak-Temme et al 2008) involved medication reconciliation and discrepancy at admission to an inpatient ward. The remaining four were at different settings or transitions of care including: emergency care settings (Marconi and Claudius 2012), medication reconciliation related interventions reported by pharmacists upon admission and transfer (Gardner and Graner 2009), transfer of patients from intensive care to a ward (Caligiuri et al 2009) and at discharge only (Ling et al 2009).

Five studies were set in Canada (Coffey et al 2009b; Coffey et al 2009c; Dersch-Mills et al 2011; Caligiuri et al 2009; Ling et al 2009), four in the US (Gardner and Graner 2009; Marconi and Claudius 2012; Stone et al 2010; Lasak-Temme et al 2008), and there was one UK study (Terry et al 2010).

Methods used and Design of study

No randomized controlled trials were identified. Six studies were prospective observational studies; four utilized retrospective chart review methods.

Outcomes of discrepancies reported

Discrepancies were studied across all interfaces either in isolation for example looking at one interface such as admissions only, or in combination.

Admission: Twenty-two to seventy-two percent of patients having an unintended discrepancy or medication error in 4 studies reporting percentages (Coffey et al 2009c; Stone et al 2010; Terry et al 2010; Lasak-Temme et al 2008); number of patients ranged from 23 to 272 in three studies, and one did not define the patient number. For the remaining two studies that did not report the discrepancy as a percentage this was reported as:

- a rate of 1.5 discrepancies per patient (Coffey et al 2009b)
- A completeness score of the admission history in comparison to a best possible medication history which was found to be 33% (interquartile range of 4 56%) in patients who were on at least one medication (non-prescription or prescription) prior to admission. (Dersch-Mills et al 2011)

Emergency setting: the number of missed non-urgent medication (which included chronic medications taken by the patient prior to admission) at a paediatric emergency unit were recorded rather than discrepancy. Before the implementation of the emergency admission pharmacist, there were 125 missed medications across 71% of 396 charts reviewed, this was reduced to 62 missed across 38.3% of the 363 charts reviewed during the implementation month and maintained at 43 missed non-urgent medications affecting 31.8% of 405 charts reviewed 6 months post implementation. (Marconi and Claudius 2012)

Transfer: an unintentional discrepancy rate of 0.53 per patient (n = 60) in transfer orders from a paediatric ICU prior to implementation of medication reconciliation (Caligiuri et al 2009) and 576 interventions made at admission and transfer to a paediatric ICU (Gardner and Graner 2009)

Discharge: For the one study identified by a conference abstract from Canada, the error rate upon discharge was reported as 43% of patients (n = 28), and 15% of medicines (n = 111) (Ling et al 2009).

Clinical assessment outcomes reported

Four studies assessed the clinical implications of the discrepancies.

Coffey et al used a three point ordinal scale (Cornish et al 2005) to assess each discrepancy for its potential to cause patient discomfort or clinical deterioration with Class 1 being unlikely, Class 2 having a potential to cause moderate, and Class 3 having a potential to cause severe discomfort or clinical deterioration. It was found that 71% of the unintentional discrepancies were class 1, 23% class 2 and 6% class 3. Terry et al used the same method in a smaller patient group of neurology patients and reported a higher proportion of class 2 and 3 discrepancies: 50% were class 1, 29% were class 2 and 21% were class 3 unintentional discrepancies. (Terry et al 2010).

Stone et al classified the discrepancies upon hospital admission using an expert consensus method to rank the adverse drug reaction risk for each error as not significant (15/36), significant (15/36), serious (1/36), life threatening (5/36) or fatal (none). This ranking method involves two

reviewers and was originally developed and used for the assessment of adverse drug events as opposed to medication errors alone (Bates et al 1995).

Gardner & Graner used pharmacists who made the intervention to clinically assess the impact of the intervention and it was found that 27% of the interventions would have minimal impact, 66% would have moderate impact and 7% would have severe impact (Gardner & Graner 2009).

Interventions reported in the literature

All studies identified had a description of a medication reconciliation intervention. Two of the included studies reported results based on changes of outcome measures by measuring discrepancy or missed medications preand post implementation of a specific intervention and are described below:

Caligiuri et al showed that a computer generated medication reconciliation form used upon transfer from ICU to a receiving ward, reduced the unintentional discrepancy rate from 0.53 per patient down to 0.10 during early implementation and 0.05 per patient at 6 months post implementation. (Caligiuri et al 2009)

Marconi & Claudis (2012) showed introduction of a pharmacist in a paediatric emergency setting, resulted in the reduction of missed non-urgent medications (which contained some of the patient's home medication) from 71% of patients pre-implementation to 38.3% (p <0.0001) and was maintained at 31.8% 6 months post intervention.

1.5.3 Discussion

Summary of main results

From a review of the literature, only 10 primary studies were found to report discrepancies at transitions of care in paediatric settings and the majority of the studies involved discrepancies at admission. Most of the studies were conducted in Canada or the US, with only one UK study in this patient group. This is unsurprising given the differences in national guidance on medication reconciliation for each of the countries.

The selection of the cohorts between the studies and method of collecting the information (retrospectively and prospectively) differed, as well as the setting which varied from emergency, neurosurgical, to Intensive Care Unit (ICU) and general paediatric inpatient settings. The studies identified included grey literature from published conference proceedings from a group in Canada looking at medication reconciliation in transfer of care settings from ICU and discharge orders in small patient groups.

As a result, the potential outcome measure of the discrepancy rate is likely to vary and undermines the generalisability of the discrepancies to a wider population of hospitalized paediatric patients.

Overall completeness and applicability of evidence

Discrepancies across the studies varied in completeness and there was no uniformity in the denominators used: studies reported unintentional discrepancies as a frequency per patient or per medication orders, which may suggest selective positive reporting of one figure over another. Only a few studies conducted at hospital admissions had clinically classified the potential harm that the discrepancies may cause if unresolved, whilst others only reported the frequency. These clinical assessments were made based on clinical judgment of the clinicians and did not employ validated tools. Three studies had used multiple judges for their studies to reach consensus, (Coffey et al 2009c; Stone et al 2010; Terry et al 2010) one study obtained scorings from individual pharmacists making the intervention (Gardner and Graner 2009) which would put the validity of the scorings in question depending on the intervening pharmacist's experience and judgment, and reliability would be low as scorings between different clinicians may vary.

Quality of the evidence and risk of bias

Using the GRADE approach (Higgins and Green 2011), where randomized controlled trials would be seen as high quality, all studies that were identified by this literature review were classed "low quality" as most fell under the category of observational studies. The review also included primary preliminary studies from indexed conference proceedings from the International Pharmaceutical Abstracts which were not peer reviewed.

In order to identify potential missing studies from published journal articles, conference reports were included in the review. All of the studies were non-randomized and conducted on small samples or a select group of patients. It was difficult to assess each study for bias. Collectively, it is probable that selective reporting of results may have occurred.

Limitations of the review

Three of the included studies in the review were identified from unpublished conference abstracts and grey literature. There was an attempt to contact authors of each abstract to see if any published full journal articles were available, without any success. This raises questions about the validity of the results and also potential bias, as the results from conference proceedings would tend to be preliminary. However, the decision to include the grey literature in the absence of a full journal article was important because without the inclusion, the two studies looking at transfer and discharge independently as an interface would not have been identified.

All of the studies were non-blinded, where service providers would be aware of the presence of the data collector or actually informed of medication reconciliation prior to collecting discrepancy information and it would be unethical to not provide the service of medication reconciliation to the patients. Hence physicians who made admission orders may have changed behavior in prescribing when they were aware of the study or had been approached regarding a discrepancy.

Implications for clinical care

Studies identified by the literature revealed a variation of methods that were used to identify medication discrepancies across the interface of transitions in care in hospital admission, transfer and discharge as well as the study settings. Few studies assessed the potential clinical impact of the discrepancies on the patient. The findings from the identified studies have not assessed occurrence of discrepancies or the clinical impact of having a medication reconciliation intervention in a wider paediatric population. Some of the studies had either investigated the clinical assessment of the discrepancies identified or compared the intervention before and after implementation; none did both collectively. Therefore the impact and significance of any interventions to reduce discrepancies on patient care and outcome remains unknown.

The current review has revealed that there is little information on medication reconciliation in children. The medication reconciliation tools and interventions used in adults may not be appropriate for use and application in children.

The recommendation that medication reconciliation should be undertaken to improve patient safety remains a challenge in paediatrics, with little evidence. Further research is required to fully understand the extent, causes and clinical significance of medication discrepancies identified at all transitions of care for this patient group.

Review conclusions

Medication discrepancies upon hospital admission, transfer and discharge occur in children as highlighted in small studies. The definitions of medication discrepancy and the actual process how medication reconciliation is carried out in children needs to be explored further, including: sources of information that are used to define what the patient was taking prior to the transition of care, and how this list is finalized. Further research is required to find out how medication reconciliation implementation can reduce medication discrepancies that have potential to cause harm. There is also a need to have medication reconciliation interventions that have been trialed and tested on a representative group of paediatric patients.

1.6 Main aims and thesis research questions

The literature review conducted in section 1.5 illustrated existing published studies on the occurrence of medication discrepancy upon hospital admission, transfer and discharge in children and the reportage of medication reconciliation interventions. However the studies that have been conducted have mainly been from Canada and the US, with the only UK study being in a small subset of the paediatric population (neurosurgical patients admitted to a paediatric hospital in Birmingham). In the UK, medication reconciliation upon discharge and post discharge has not been researched so far.

1.6.1 Research Question

The research questions for this thesis were: -

- "Do children admitted and discharged from hospital experience discrepancies at the point of admission, discharge and post discharge?"
- "Do they require medication reconciliation to prevent potentially significant clinical outcomes?"
- "At which points of transition should an intervention be put into place to prevent these discrepancies?"

1.6.2 Overall aim

The overall aims of this thesis were to identify the epidemiology, causes and clinical significance of discrepancies that occur at hospital admission in the paediatric population across England (Chapter 2) and post hospital discharge for children discharged from hospital to their GPs (Chapter 4). Chapter 3 was an interim preliminary study to chapter 4 which aimed to assess the accuracy of discharge letters by evaluating the procedure used to reconcile medications at discharge, timeliness of receipt from the GP. Chapter 3 also explored the GP surgery reconciliation procedures in children based on the CQC report (CQC 2009). The intentions of identifying the epidemiology and clinical significance of discrepancies in these particular points were to build the evidence base on the effectiveness of conducting medication reconciliation for children at these points of transfer of care and evaluate what particular interventions were required at each point.

Further details of the aims and objectives of each chapter are discussed at the beginning of each chapter.

1.7 PhD candidate's contribution and overall methodological design for the thesis

1.7.1 PhD candidate's background and contribution to the thesis

The PhD candidate Chi Huynh is a qualified pharmacist from a hospital pharmacy background. Prior to the award of a PhD studentship, the candidate had completed one year of pre-registration pharmacy training and worked for one year as a rotational junior pharmacist at a teaching hospital in London.

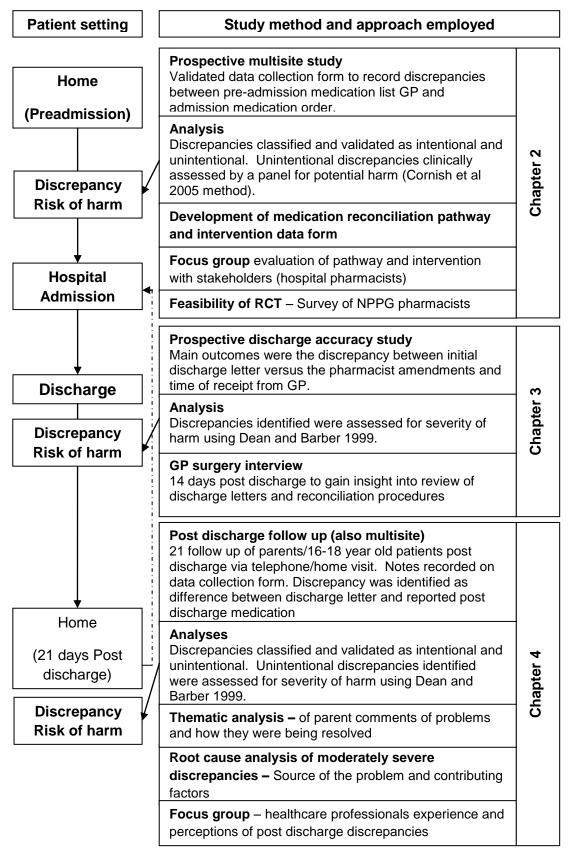
The candidate entered the project when funding from the Neonatal Paediatric Pharmacist Group was approved to conduct a "transitions in care literature review" and "multisite medication reconciliation at hospital The candidate designed literature review, and was admission" study. responsible for the management of the data collection and analysis of results. The original plan intended was to design a "medication reconciliation" at admission" complex intervention for children based on the findings from the results and design a Randomised Controlled Trial (RCT) to assess its effectiveness. The results from the preliminary study and feasibility assessment suggested that a RCT was not feasible and that there the GP records did not reflect the patients. The thesis and research question was changed to observe and explore interface of care issues that a child experienced from home to hospital and hospital to home. The candidate subsequently conceived the idea of designing a discharge and post discharge study to observe the issues children discharge from hospital had

with their medications post discharge. A grant application for was written and submitted by the candidate and was successful.

1.7.2 Overall methodological design of the thesis studies

The studies of this thesis was chronologically arranged to represent a child's journey from hospital admission to discharge and beyond. Figure 1 shows an outline of the various methods adopted and applied to observe the medication discrepancies and potential outcomes in the absence of medication reconciliation and factors affecting a child at various interfaces of care.

Figure 3 – A summary flow diagram of the overall chronological methodological design of the thesis studies



1.7.3 Assessment of the methodological approach employed for the thesis studies

A variety of methods were employed to ensure that all information in the complex process of measuring the impact and nature of medication reconciliation related issues in children were robust.

The use of a "pharmacoepidemiology to study medication errors" approach (Strom ed. 2005) was adopted to establish the incidence of medication discrepancies at each interface of care: admission, discharge and post hospital discharge. Each stage of these studies were designed to capture the primary information prospectively, via a data collection form each transition in care interface.

At admission, the data collection form used by Terry et al (2010) in the single site study was adapted for use in the multisite admission study in chapter 2. Adaptations were made by the PhD candidate after discussion with the team and it was decided that the GP was going to be used to reflect the paediatric patient's pre-admission medication list, as opposed to basing the list on the GP and secondary care prescriber for outpatient obtained medications. To ensure that the data collected from each of the sites were consistent, each site's data collector across the four sites in London, Birmingham, Leeds and London, were all trained to collect the information systematically and the first few data collection forms were reviewed to ensure consistency. A pharmacist recommended therapy section was also added to the data collection form, to capture the finalised drug list after clinical pharmacist consultation with the prescriber. Patients were not

Chapter 1

chosen by random, and every consecutive patient who met the inclusion criteria and was admitted long enough for the data collection to take place was included in the study to minimise selection bias. The sites involved in the study were limited to four hospitals in England due to funds and resources; however, each site had differing systems of practice in place.

At discharge, a prospective sampling of all discharges occurring within a 5 week study period was conducted at a single London hospital site which provided not only tertiary care, but also local secondary care to its local boroughs. A data collection form was developed by the PhD candidate and reviewed by supervisors to ensure relevant information was captured. This was piloted, and the first few data forms reviewed.

At post hospital discharge, each site was provided with a protocol on how to recruit and consent patient's for the post discharge study. A patient information leaflet was utilised and each member of staff delegated were GCP trained and also received in-house training by the PhD candidate who co-ordinated the study. To ensure consistency and appropriateness of use, a data collection form was developed and reviewed by the chief investigator of the study (clinical supervisor) and submitted for ethical review. The study was designed to follow up parents/patients aged 16 -18 years 21 days post discharge to provide time for parents/patients aged 16-18 years to arrange for further supplies of medication with their GP in primary care as hospitals would normally provided 7 – 14 day supply or an original pack of discharge medication. Each discrepancy identified was classified and validated as unintentional or intentional by the PhD candidate and a clinical pharmacist.

The use of a single type of instruments and data collection forms to establish the incidence of medication discrepancy for the admission and post discharge study across the many sites ensured that information was collected systematically. This ensured that the incidence calculated was reliably captured across the sites. This incidence figure derived from the data collection did not explain or provide observations on how this affected patients in terms of potential for harm. Hence, at each interface of care and for each of the unintended discrepancies identified, the potential impact of harm each patient had was assessed using analytical clinical assessment methodology.

At admission, the Cornish et al (2005), methodology adaptation by Terry et al (2010) was used to, which was to invite 5 clinicians from the hospital setting to discuss, come to a consensus and class the discrepancies by order of severity from Class being unlikely to be harmful or class 3 potentially severely harmful. As this method was time consuming to set up and due to time constraints, for the discharge and post discharge study, a validated severity scoring method by Dean and Barber (1999) was adopted where clinicians were sent the discrepancies and asked to severity score the discrepancies individually and find a mean score. The post discharge study extended the impact analysis by conducting Root Cause Analysis for discrepancies that were assessed to be moderately harmful. Root Cause Analysis was a useful tool to find out possible explanations and common causes of discrepancies to identify issues with the system, however this was limited by the information retrieved by the investigator and artificial cut off

point due to limited project time scales, and in the case of the project this was the PhD candidate.

Finally, appropriate techniques were purposefully chosen in a timely fashion to explore current practice (e.g. GP surgery procedures), healthcare professional's concept and perception of medication reconciliation parent and patients comments on problems as appropriate. These perceptions, evaluations, beliefs and reportage of experiences were not captured by the data collection at each interface of care and hence survey, semi-structured interviews and focus groups were adopted to explore these issues.

In order to capture the practice of medication reconciliation in children at hospitals across the UK outside the multisite admission study, the PhD candidate sought permission to obtain a database from the Neonatal and Paediatric Pharmacist Group (NPPG) to identify pharmacists to survey. The survey was designed on an online interface using survey monkey and participants were invited via email. The advantages of this were that there was no time delay with posting a paper survey, but also had the disadvantage that clinical staff may not have easy access or time available to complete the survey. The limitations of selecting pharmacists from a specialist group such as the NPPG were that not all pharmacists who work on paediatric wards were members. Although this was a limitation, the database of members had a coverage of specialist and non-specialist hospitals and covered many hospitals across the UK.

A semi-structured interview in chapter 3 was designed to gain insight into the review process of discharge letters from GP. The interview schedule was designed by the PhD candidate and reviewed by clinical pharmacists and also a GP. The strengths of requesting to talk to the administrator or manager of the surgery were that the staff were more likely to be available for interview and hence increasing the response rate. This however, limited the findings based on the procedures at the surgery and may not have reflected the GP's actual approach to queries relating to post discharge discrepancies. The thematic analysis of comments that were made during the post discharge follow up of parents in addition to the quantitative information was conducted to explain parental experiences and observations of post discharge problem solving, not just by the GP, but also by the hospital healthcare professionals or community pharmacists.

Focus group methodology was used at the end of the admission study for two purposes. For the admission study (section 2.4), a focus group was employed to obtain in depth insight into pharmacists views on medication reconciliation at admission, and also the acceptability of an intervention and pathway that was piloted. This was selected rather than individual in-depth interviews with staff to capture sharing of various viewpoints and opinions from all participants. The participants who were selected were the staff involved in the data collection, pilot of the intervention as well as the site investigation lead pharmacists. The post hospital discharge focus group was conducted to gain further understanding and insight into experiences that various healthcare professionals who looked after the patient had with

Chapter 1

respect to problems that occur in practice. The participants were also asked for their views on possible solutions to these post hospital discharge issues. The focus group participants were invited on the basis that they had taken part in the severity assessment earlier with the exception of one community pharmacist.

In summary, many methods were used to explore many different aspects of a child's journey in and out of hospital as feasible. An pharmacoepidemiology approach was used to find the epidemiology of the discrepancies to highlight a clinical risk at various points of transition. Analytical techniques which asked relevant healthcare professionals to assess the potential clinical impact in the absence of an intervention was used to provide a robust indication. Surveys, interviews and focus groups were employed as appropriate to capture observations of current practice and also gather insight into healthcare professional views surrounding the interface problems issues and evaluation of interventional designs.

Chapter 2 - A multi-centre study of pharmacy led medication reconciliation upon hospital admission in children

Aims and Objectives

The aims of this chapter were to find out what was the epidemiology of medication discrepancies upon hospital admission for paediatric patients in the UK and of the unintended discrepancies found, how many would be clinically significant and likely to lead to patient deterioration or harm? The secondary aim was to establish a paediatric specific interventional pathway for conducting medication reconciliation in children and to evaluate this by gathering feedback from staff.

In order to address the aims, a four stage study was proposed: -

Stage 1 – Observation and clinical assessment of discrepancies identified by medication reconciliation upon hospital admission

A prospective observational study was conducted where medication reconciliation was conducted across 4 hospital sites of paediatric patients admitted into hospital and discrepancies between the pre-admission medication and admission medication orders were recorded, of which the unintended discrepancies were clinically assessed by a panel of healthcare professionals (see section 2.2).

Stage 2 – Defining, development and piloting of a derived medication reconciliation pathway and form

Utilising the findings from the previous phases of the study, a medication reconciliation pathway and form was designed for pharmacists to use, and its use was piloted across the study sites (see section 2.3)

Stage 3 - Evaluation of the derived medication reconciliation pathway –

Eight pharmacists involved in the study and the site leads for the multisite study were invited to a focus group (see section 2.4)

Stage 4 – Feasibility of RCT (see section 2.5)

A survey of paediatric hospital pharmacists across the UK was conducted to ascertain the current policies, practices and levels of hospital admission MR services for children admitted to NHS hospitals in the UK. If the survey results suggested that there were no admission MR services for children in England this would support the case for conducting an RCT comparing a MR service against routine care. If the survey suggest that admission MR services were in place at NHS hospitals in the UK, a randomised control trial to evaluate the effectiveness would not be feasible.

2.2 Multi-site study – Identification of medication discrepancies upon hospital admission for children and clinical significance

The aim of the clinical phase of the study was to investigate the occurrence and incidence of medication discrepancies relating to children on admission to hospital in a wide setting nationally, suitable to support generalisability, and identify possible clinical implications. In order to fulfil the aims, the following objective was proposed: a prospective multisite study of a pharmacist-led medication reconciliation service, where discrepancies between the GP current drug history (GPRxs) and admission medication orders (AMOs) from the initial hospital drug chart (referred to as "GPRx v AMO" discrepancies) were identified and any unintended changes between the GPRx and AMO were clinically assessed. Prescribers of AMOs were Chapter 2Medication reconciliation upon hospital admission in childrenasked to confirm on each occasion whether they had intended to continue

unchanged the pre-admission medication prescribed by the patient's GP. Where the GPRx and the AMO differed and this was not the intention of the prescriber these are described in this study as 'unintentional discrepancies'.

2.2.1 Methods

Study design

The study was a prospective multisite study where pharmacists at four hospital sites conducted medication reconciliation using a standardised data collection form.

Setting

The paediatric hospital wards across all available specialities of four hospital sites in Birmingham, Leeds, London and North Staffordshire in the UK. The sites provided secondary as well as specialist tertiary care to paediatric patients.

Study duration

Five month prospective data collection period from January 2011 – May 2011.

Data collection at ward level

The study cohort included patients that were:

- admitted during the study period
- available for full medication reconciliation by the study team during working hours
- prescribed at least one long term medication

Patients were excluded from the study if:

- they were 19 years or older
- the parent-carer was not available for interview
- the medication information sources were not accessible at the time of the data collection
- if the data collection could not be completed for practical reasons such as the admission taking place out of hours in the evenings or during weekends.

Approximately 60 paediatric patients from each of the study sites were included in the study. Long term medication was defined as a medication that was prescribed for the patient and taken on a repeat basis for three months or longer. A pre-assessment form was used to screen if the patient was eligible for inclusion in the study (see Appendix A).

Once a patient was identified as fulfilling the criteria for inclusion, medication reconciliation was then conducted or overseen by the study clinical

pharmacists or research pharmacist and this was conducted based on the West Midlands Medicines Reconciliation Guide and Report form, (see Appendix B). Information concerning the patient's ward, specialty, diagnosis, age, weight was recorded.

The data collected included medication information collected from the following sources: -

- A semi-structured interview with the parent or carer of the patient to obtain a medication history and subsequently securing their permission to contact their GP
- The determination of the GPRx obtained by telephoning the patient's GP practice.
- Recording details of the Patient's Own Drugs (PODs) that were brought into hospital on admission
- Recording the initial AMOs from the hospital drug chart (prior to clinical pharmacist input)
- A pharmacist's recommended therapy was established based on the information present and their clinical judgment as to what the patient should be prescribed in terms of long term medications at the time of admission
- The length of time it took to obtain the information required was recorded.

Definition and nomenclature (naming of) discrepancies

A discrepancy was defined as a change between the patient's on-going medication record immediately prior to admission (GPRx) compared to the initial drug chart medication (AMOs) In the UK, patients who require long term medication at home will usually have their medication records kept by their registered General Practitioner. It was on this basis that the current and ongoing GP medication list (GPRx) was chosen to represent the pre-admission medication.

Any discrepancies that were found between the GPRxs and AMOs (referred to as "GPRx v AMO") are described as either 'intentional' or 'unintentional'; where unintentional is when the prescriber of the AMO was unaware that they were modifying the GP prescription and believed that they were simply continuing the pre-admission prescription(s).

For clarity these discrepancies are described as: -

- "GPRx vAMO" collective discrepancies
- "GPRx v AMO(i)" intentional discrepancies
- "GPRx v AMO(u)" unintentional discrepancies

Outcome measures

Establishing the frequency and classification of discrepancies

As part of the data collection, "GPRx v AMO" discrepancies identified by the pharmacists conducting the data collection and classified as either unintentional or intentional were presented to a panel of lead pharmacists for

validation. The incidence of patient "GPRx v AMO" unintentional discrepancies was calculated using the formula below: -

Number of patients with at least one GPRx v AMO(u) × 100 Number of patients*

*Over 5 month study period

All the "GPRx v AMO(u)" unintentional discrepancies were then clinically assessed.

Clinical significance assessment of unintended discrepancies between the GP record and initial admission medication orders

All "GPRx v AMO(u)" unintentional discrepancies identified were clinically assessed using the methodology used by Terry et al (2010) adapted from Cornish et al (2005).

A panel of experts consisting of two clinical pharmacists, two hospital doctors and a medicines management nurse (the "Clinical Assessment Panel") met and discussed the "GPRx v AMO(u)" discrepancies. Each discrepancy was considered on a case by case basis and the patient's age and diagnosis were provided to the panel.

The Clinical Assessment Panel was asked to rank each "GPRx v AMO(u)" discrepancy to one of the following three classifications based on a theoretical scenario where the discrepancies was left unchanged over a period of 7 days:

- Class 1: Unlikely to cause patient discomfort or clinical deterioration
- Class 2: Potential to cause moderate discomfort or clinical deterioration
- Class 3: Potential to result in severe discomfort or clinical deterioration

In the case where there was no GP record at all or in the case where deviating from the GP record would be beneficial – these were ranked as below: -

- Class 1* A change with a minor potential to improve patient comfort or provide clinical benefit
- Class 2* A change with potential to result in moderate improvement patient comfort or clinical benefit
- Class 3* A change with the potential to result in major improvement in patient comfort or clinical benefit

A star has been added to the beneficial classifications for the purpose of distinguishing against the original definition.

The incidence of the number of patients who had moderate or severe "GPRx v AMO" unintentional discrepancies was calculated as follows: -

Number of patients with moderate or severe "GPRx v AMO(u)* Number of patients* *Over 5 month study period

Frequency of medication type (as per BNF chapter) in relation to medications ordered during the data collection and "GPRx v AMO(u)" unitended discrepancies

The "GPRx v AMO(u)" discrepancies identified by the data collection were classified and grouped into the main chapters of the BNFC with the purpose of identifying the speciality where most discrepancies occurred; taking into account how frequently prescribed the class of medication was prescribed in the complete data set.

Frequency of discrepancies across the four study sites

The results of the data collection were broken down into the four individual sites to assess if discrepancies occurred across the study sites and to determine if all sites had patients who had potentially harmful unintentional discrepancies.

2.2.2 Results

Patient demographics

Over a 5 month period, 244 patients (approximately 60 patients or more per site) were admitted to the study, and 1004 medications regimens were recorded. The age range of the patients was from 1 month to 16 years of age (median age of 5 years, IQR 1.5 years to 11 years 3 months). In terms of ward speciality the majority of the patients were considered to be primarily associated with general paediatric medicine followed by surgery, respiratory and neurosurgery. Other specialities were represented including: neurology, renal, cardiology, orthopaedics.

Frequency and classification of "GPRx v AMO" discrepancies

From the 1004 medication regimens identified from the 244 patients, the pharmacist data collectors identified 582 "GPRx v AMO" medication discrepancies affecting 203 patients. By reference to the hospital prescribers the 582 "GPRx v AMO" medication discrepancies were classified as either intentional or unintentional by the pharmacist data collectors and further reviewed and validated by the site leads to ensure consistency (see figure 3 for details).

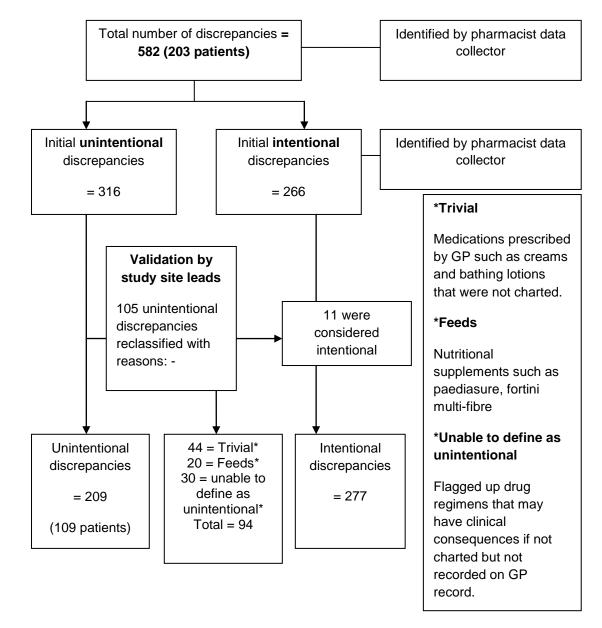


Figure 4 – Classification procedure of "GPRx v AMO" discrepancies

After the validation process, of the 582 "GPRx v AMO" discrepancies, 209 were classified as unintentional, 277 were intentional and 94 were reclassified as either trivial, feeds or other (other = discrepancies that the team were unable to classify because the drug regimen was not on the GP record/not issued by the GP recently, nor written up on the hospital drug chart but flagged up by the pharmacist or patient). The 209 "GPRx v

AMO(u)" unintentional discrepancies affecting 109 patients were clinically assessed.

Incidence of patients with at least one "GPRx v AMO(u)" unintentional discrepancy

The patient incidence of having at least one "GPRx v AMO(u)" unintentional discrepancy for all patients in the study was:

Number of patients with "GPRx v AMO(u)" discrepancies Total number of patients seen in 5 months = $\frac{109}{244}$ × 100 = 45%

This incidence rate only accounts for the patients who were taking (or expected to be taking) long term medication prior to hospital admission and who were seen during pharmacy operational hours.

Clinical significance of "GPRx v AMO(u)" unintentional discrepancies

The 209 "GPRx v AMO(u)" unintentional discrepancies representing 109 patients were classified using the Cornish methodology (Cornish et al 2005) and it was found that 189 drug discrepancies (100 patients) were unintentional discrepancies that were classifiable into the *"harm"* classifications.

Hence the revised incidence of the number of patients with at least one unintentional discrepancy was: -

```
Number of patients with "GPRx v AMO(u)" discrepancies100Total number of patients seen in 5 months=\frac{100}{244} × 100 = 41%
```

The number of "GPRx v AMO(u)" discrepancies and patients per each clinical classification are described below: -

• Number of Class 1 "GPRx v AMO(u)" discrepancies = 57 (30%)

*40 patients (40%)

Number of Class 2 "GPRx v AMO(u)" discrepancies = 89 (47%)

*62 patients (62%)

• Number of Class 3 "GPRx v AMO(u)" discrepancies = 43 (23%)

*28 patients (28%)

*Note the number of patients did not tally to 100 as any single patient may have more than one "GPRx v AMO(u)" discrepancy.

The figures above show the individual numbers of patients per class of "GPRx v AMO(u)" discrepancy. When the discrepancies for the 100 patients were considered collectively, and only the most serious discrepancy was taken into account (i.e. where the patient had more than one "GPRx v AMO(u)" discrepancy) then the number of patients where the highest class of discrepancy are: -

- 22 patients where Class 1 is the most serious "GPRx v AMO(u)" discrepancy (22%)
- 50 patients where Class 2 is the most serious "GPRx v AMO(u)" discrepancy (50%)

 28 patients where Class 3 is the most serious "GPRx v AMO(u)" discrepancy (28%)

Hence 28 patents had at least one "GPRx v AMO(u)" discrepancy which was serious, 50 patients had at least one discrepancy that was moderately serious.

The overall incidence of patients with at least one moderate or severe "GPRx v AMO(u)" unintentional discrepancy was: -

78 patients (with at least one moderate or severe GPRx v AMO(u) unintentional discrepancy) × 100 = 32%

244 patients (seen during the study period)

The 95% confidence interval for the incidence was a value from 26.1 to 37.8%.

Frequency of medication type (as per BNF chapter) in relation to the medications ordered during the data collection and unintentional discrepancies

The frequency of occurrence of all medication identified during this study, in descending order, by BNF chapter were: central nervous system; gastrointestinal system; respiratory system. However, when the drugs that were identified as "GPRx v AMO(u)" discrepancies were grouped into BNFC chapters, it was shown that the most frequently prescribed drugs in descending order were: respiratory system; gastrointestinal system; central nervous system. Table 5 provides a breakdown of the medications ordered per BNFC main chapter from the entire data set and subset of "GPRx v AMO(u)" discrepancy.

Table 5 Medication orders and "GPRx V AMO(u)" unintentional discrepancies categorized per BNF chapter

			GPRx V AMO Unintention Discrepancies			tentional
		Total number of medication orders (percentage)	Class 1	Class 2	Class 3	Total
BNF Chapter	1. Gastrointestinal system	189 (18.82)	10	14	7	31
	2. Cardiovascular system	53 (5.28)	1	1	2	4
	3. Respiratory system	178 (17.73)	4	51	11	66
	4 Central Nervous System	210 (20.92)	14	5	11	30
	5. Infection	71 (7.07)	3	9	4	16
	6. Endocrine system	50 (4.98)	1	2	5	8
	7. Obstetrics, gynaecology, and urinary-tract disorder	1 (0.10)	-	-	-	-
	8. Malignant disease and immunosuppression	16 (1.59)	-	-	-	-
	9. Nutrition and blood	122 (12.15)	21	5	2	28
	10. Musculoskeletal and joint diseases	26 (2.59)	2	1	0	3
	11. Éye	4 (0.40)	-	-	-	-
	12. Ear, nose and oropharynx	1 (0.10)	-	-	-	-
	13. Skin	36 (3.59)	1	0	0	1
	14. Immunological products and vaccines	1 (0.10)	-	-	-	-
	15. Anaesthesia	4 (0.40)	0	0	1	1
	Unknown	42 (4.18)	0	1	0	1
	Total	1004	57	89	43	189

Frequency of discrepancies across the four sites

The results of the data collection across the four sites was stratified according to site to determine if all four sites experienced discrepancies and had potentially clinically significant discrepancies in the absence of medication reconciliation. The results are shown on table 6.

Site	Dirminghom	London	Leeds	North Staff.	Total
Site	Birmingham	London	Leeas	Staff.	0.1.1
Number of patients on LTM	60	63	60	61	244
Number of medication regimens					
(All that was recorded)	236	282	174	312	1004
Number of total GP v AMO					
	113	190	104	175	582
discrepancies recorded % of total GP v AMO	113	190	104	175	302
discrepancies (total					
discrepancies divided by the					
number of medication regimens)	47.88	67.38	59.77	56.09	
Average medications per patient	47.00	07.30	59.77	50.09	
on LTM	3.92	4.48	2.9	4.72	4
Number of patients with an	5.92	4.40	2.9	4.72	4
unintentional GP v AMO					
discrepancy (harmful)	11	37	26	26	100
% patients with an unintentional			20	20	100
discrepancy (harmful)	18.33	58.73	43.33	42.62	
Total number of unintentional					
GP v AMO discrepancies					
(harmful)	12	75	42	60	189
(narmal)	12	10	74	00	100
% of unintended discrepancies					
(out of all medications)	4.68	13.12	14.94	9.03	
Number of patients with Class 2					
or 3 discrepancies (Clinically					
significant unintentional					
discrepancies)	6	27	21	24	78

Table 6 Stratified results for each of the four study sites

2.2.3 Discussion

The results from the multisite study demonstrates that "GPRx v AMO(u)" medication discrepancies occurred at hospital admission for paediatric patients in all 4 study sites. The overall incidence of patients associated with these unintentional changes, and classified as having the potential to cause moderate or severe harm if left unchanged was 32%. This is the first multisite and non-speciality specific study in the UK to demonstrate that children admitted to hospital experience unintended GPRx v AMO medication discrepancies upon hospital admission prior to pharmacist conducted medication reconciliation. In comparison to adult studies, the study by Cornish et al (2005) showed that 38.6% of adult patients admitted to hospital significant unintended discrepancy utilising the same methodology. A paediatric study from Coffey et al conducted in a general paediatric setting showed a relatively smaller proportion of patients with unintended discrepancies which was reported as 22%.

The study methodology used in this present study was different from those conducted by Cornish et al and Coffey et al in respect of the sources used to define the pre-admission medication (PAM) list which was then compared with the AMO. Cornish et al and Coffey et al based the PAM on a list derived by study pharmacists; however this present study used the GP record to identify PAMs. Whilst it is known that 1 in 8 children on long-term medicines receive medication prescribed by more than one source e.g. GP and hospital consultant (Terry, 2010) patients at home are the responsibility of their GP

Chapter 2 Medication reconciliation upon hospital admission in children and as a consequence it may be expected that their records are up to date and complete. There were cases in this present study where the discrepancies between GP and drug chart ("GPRx v AMO(u)") could not be classified using the "potential for harm" definition, reflecting that the GP did not hold the complete record. The two previously published studies did not observe how accurate, or sensitive, each source of information was compared to the finalised pre-admission medication list.

This present study supports the need for medication reconciliation to be conducted after the AMO is written up and confirms that medication reconciliation is required for hospitalised children in a general setting, irrespective of clinical speciality.

2.2.4 Conclusions

The study demonstrated that discrepancies occurred in hospitalised children in 4 English hospitals between their GPRx and AMO records. This was the first UK study to confirm this important finding. The overall incidence of patients with at least one "GPRx v AMO(u)" discrepancy, with potential for moderate or severe clinical risk, was 32% from the entire study cohort of children who were admitted and who were prescribed long term medications prior to admission. 78% of the "GPRx v AMO(u)" discrepancies had the potential to cause moderate to serious harm if left unresolved. This finding confirms the need for medication reconciliation within this cohort. The medication reconciliation process should identify the patient's pre-admission medication as a pre-requisite to identifying the most suitable drug regimens following admission.

At this stage of the multisite study, the findings from the study suggest that paediatric patients admitted to hospital experience discrepancies identified during the data collection by comparing the patient's initial medication list from the GP and the hospital medication orders AMOs. A clinical assessment also suggests that there is harm associated with these discrepancies in the absence of medication reconciliation. The next stage of the study was to develop a medication reconciliation intervention and pathway suited to clinical practice based on the results and findings from the multisite study as the data collection form (see appendix A and B) was suited for audit purposes and collecting information, but impractical to use to real life practice.

2.3 Defining, development and piloting of a derived medication reconciliation pathway and form

2.3.1 Aims and objectives

The aims and objectives of this stage of the study were: -

- To utilise the data presented in chapter 2.2 to identify how medication reconciliation in children should be conducted by: -
 - Analysing the sensitivity of each source of information that was used to conduct medication reconciliation from the data collection forms
 - Identify anomalous findings from the results and implications for the model medication reconciliation process
 - Assess the discrepancies that occurred between the pharmacist recommended therapy (recorded on the data collection form) and the AMO and compare this to the GP preadmission medication history
 - Presenting the data to the multisite study team for review and comments
- Utilising the findings from the previous phases of the study, design a medication reconciliation pathway and form, for pharmacists to use, and pilot its use across the study sites.

2.3.2 Method

Assessment of sensitivity of each source of information obtained during data collection against the pharmacist's recommended therapy

The data collected for the 189 paediatric patients on long term medications from the 5 month prospective observational study who had at least one "GPRx v AMO(u)" discrepancy as described in the multi-site study were reanalysed with an alternative outcome measure described below.

The pharmacist recommended therapy was taken as the most accurate reconciled medication list and each source: GP; parent-carer interview and patient own drugs were compared against this new standard. The percentage of medication for each source of information which matched the pharmacist recommended therapy was calculated using the following formula: -

Number of medications that matched the pharmacist recommended therapy

Number of "GPRx v AMO(u)" discrepancies in total × 100

For the sources of information that had the highest match against the pharmacist's recommended therapy, the data was further explored to identify which other data sources could provide additional relevant information.

The sensitivity was subsequently calculated as: -

Number of medications that matched the pharmacist recommended therapy × 100

Number of occasions where the source was available

Extraction of anomalous data from the multisite study

The data collected from the multi-site admission study (chapter 2.2) were explored for anomalous data that did not fit the expected trend. The anomalous data that were explored and extracted included:

- ""GPRx v AMO(u)" unintentional discrepancies where deviating from the GP record was considered to have potential for a patient benefit.
- "GPRx v AMO(u)" unintentional discrepancies where the pharmacist recommended therapy were different to, and did not match any of the sources of information collected during the data collection (GP, Drug Chart, parent-carer interview, and PODs).
- Other findings from the data. For example discrepancies as a result of the GP record being ambiguous, with examples such as "use as directed" and medication reported in the medication history, but not written up on the drug chart that were long term but not frequently used except for in emergency.

Defining the discrepancy by comparing the pharmacist recommended therapy against the initial drug chart (Pharmacist v AMO)

Data collection and defining of the "Pharmacist v AMO" discrepancy

The data collected for the 244 paediatric patients prescribed long term medications from the 5 month prospective observational study as described in chapter 2.2 were used with an alternative outcome measure described below:

The pharmacist recommended therapy was compared with the AMOs and discrepancies were identified. To avoid confusion, the discrepancies between the pharmacists-recommended therapy versus the AMOs will be referred to as the "Pharmacist v AMO" discrepancies. These were then classified into intentional "Pharmacist v AMO(i)" and unintentional "Pharmacist v AMO(u)" discrepancies based on the information collected In this definition an AMO was either 'intentional' or 'unintentional' compared with the GPRx (see above), and this defines this aspect of the discrepancy e.g. Pharmacist v AMO(i) - there was a clear decision from the hospital prescriber to change existing therapy and this disagrees with the pharmacists judgement; Pharmacist v AMO(u) - the pharmacist and AMO disagree and the AMO prescription was an unintentional change from the GPRx.

The "Pharmacist v AMO(u)" unintentional discrepancies were then considered for clinical assessment using the method from Terry et al (2010), adapted from the Cornish method (2005). The patient incidence of the

"Pharmacist v AMO(u)" unintentional discrepancies in patients was calculated using the following formula: -

Number of patients with at least one "Pharmacist v AMO(u)" unintentional discrepancy* × 100

Number of patients*

*Over 5 month study period

Clinical assessment method

The "Pharmacist v AMO(u)" unintended discrepancies were summarised into a descriptive commentary, and the patient's age, weight, diagnosis and indication were provided to the assessors. Data were presented in an MS Excel 2007 spreadsheet where one row represented one discrepancy. The anonymised spreadsheet was sent to the clinical assessment panel judges individually via email (the same clinical assessment panel judges that assessed the "GPRx v AMO(u)" unintentional discrepancies earlier see section 2.2). Each judge was asked to score the potential harm of each "Pharmacist v AMO(u)" discrepancy on a case by case basis, based on a theoretical scenario where the discrepancies were left unchanged over a period of seven days.

The classifications of the severity were: -

- Class 1: Unlikely to cause patient discomfort or clinical deterioration
- Class 2: Potential to cause moderate discomfort or clinical deterioration

Class 3: - Potential to result in severe discomfort or clinical deterioration

The expert judging panel members had received training/experience in scoring the discrepancies during a previous meeting comparing the GP record (GPRx) versus the AMO (drug chart).

The scores were sorted and stratified into the level of agreement between the final judges. Where all 5 judges agreed on the final scores, these were confirmed as the final classification. For the "Pharmacist v AMO(u)" unintentional discrepancies where the agreement was 4 judges or less, these were evaluated by the study site lead pharmacists/study pharmacists (ST, DT, KW, HH, CH) during a team meeting where the final score was discussed until consensus was reached.

The incidence rate of the number of patients who had moderate or severe "Pharmacist v AMO(u)" unintentional discrepancies was calculated as follows: -

Number of patients with moderate and severe Pharmacist V AMO(u) unintentional discrepancies*

Number of patients*

× 100

*Over 5 month study period

Design of the model paediatric specific medication reconciliation pathway and data collection form

A model paediatric medication reconciliation pathway and data collection form was developed after reviewing the results from the multisite study. The form was designed by the research pharmacist CH, and sent to the multisite study team of lead pharmacists (HH, AL, DT, ST, KW) for review. Comments were received and relevant amendments and adjustments to the pathway and intervention form were made. Please refer to Appendix C and D for the model medication reconciliation pathway and data collection form.

Pilot data collection using the model medication reconciliation pathway and data collection form

Each of the four study sites (Birmingham, Leeds, London and North Staffordshire) were required to select an opportunistic sample of 20 patients admitted to paediatric wards who were taking long term medication over the period of Monday 20th February – Friday 16th March 2012 and conduct a full medication reconciliation on each patient. Pharmacists were selected as the healthcare profession to conduct the pilot data collection based on NICE guidance for medication reconciliation on admission, where it was recommended that pharmacists were involved in medication reconciliation. The pharmacist data collectors were asked to conduct the medication reconciliation is of pre-admission medications using one of the three defined pathways in the following order of selection depending on source availability:

- Pathway A (parent-carer first)
- Pathway B (POD first) if parent-carer not available
- Pathway C (Medical notes first) if neither parent-carer or PODs not available

Data were recorded on the data collection sheet provided (see Appendix E and F respectively for further details). For the purposes of comparison, all patients' initial drug chart orders (prior to any pharmacist intervention or screening) were also recorded, to evaluate the discrepancies identified. A discrepancy in this part of the study was defined as a difference between the final pharmacist concluded medication lists of pre-admission medications as recorded on the intervention data collection form versus the AMO ("Intervention v AMO"). All sources of information were recorded for the purposes of identifying which were used by the pharmacists during the proposed model pathway to reconcile the patient's admission. In the pilot and evaluation of the proposed new model pathway, the pharmacists had some choice over which sources of information they obtained and used to determine the patient's medication requirements. This is in contrast to the main study data where the methodology required obtaining and considering a definitive list of sources. The term 'Intervention' is used to identify the pharmacist's reconciled medication list during the pilot and assessment of the proposed model pathway.

Inclusion and exclusion criteria

The same inclusion and exclusion criteria as the admission multisite study (see section 2.2.1) was used.

Combination and comparisons of medication discrepancies identified "GPRx v AMO, "Pharmacist v AMO" and "Intervention v AMO"

The results from the "GPRx v AMO" discrepancies, "Pharmacist v AMO" discrepancies and the "Intervention v AMO" discrepancies were tabulated for comparison. An association between the two methods of defining discrepancies on the data set from the main multisite study was used for the "GPRx v AMO" and "Pharmacist v AMO" discrepancies and was tested using Pearson Chi-Squared test and the Cohen Kappa statistic.

2.3.3 Results

Assessment of sensitivity of each source of information against the pharmacist's recommended therapy from the main multisite study

A comparison of the pharmacist recommended therapy (a decision the pharmacist made at the conclusion of the medication reconciliation process) against the sources of information used showed that the parent-carer provided the most accurate information by matching 81% of the pharmacist recommended therapy. The GPRx matched the pharmacist's recommended therapy in 70% of cases whereas the PODs only matched in 28% of cases. A detailed breakdown is shown in Table 7.

Table 7 Number and percentage of matches for each source of information to when compared against the pharmacist's recommended therapy

Source of Information	Number of matches to the pharmacist recommended therapy	Percentage matching the pharmacists recommended therapy
Parent-carer	153	153/189 X 100 = 81%
GPRx	132	132/189 X 100 = 70%
POD	53	53/189 X 100 = 28%

Thus using the pharmacist-recommended therapy as the standard, the best matched source (parent-carer) would have identified 81% of all the medication being taken by the child. In order to reconcile the remaining 19% where the parent-carer interview did not match with the pharmacist's recommended therapy – 22/36 (61%) would have been resolved via GP input and 3/36 (8%) via the admitting doctor's order only. In 11/36 (31%) cases, there were conflicting information and the pharmacist made the recommendation based on clinical judgement.

If the information from the GPRx was taken as the only source of information used to take the medication history (which was the second best source of information that matched the pharmacist's recommended therapy) this would have provided accurate information in 132 out of 189 (70%) required medications. For the 57 (30%) of missing data, 43/57 (75%) would have been resolved via parent-carer input, 12/57 (21%) would have been resolved with patient own drugs, and 3/57 via the admitting doctors only. In

11/57(19%) cases, there were conflicting information and the pharmacist made recommendation based on clinical judgement.

Extraction of anomalous data from the multisite study

"GPRx v AMO(u)" unintentional discrepancies where deviating from the GP would have been a beneficial outcome rather than harmful

Of the 209 "GPRx v AMO(u)" unintentional discrepancies identified in the main study, only 189 were classifiable using the Cornish methodology of potential to cause clinical deterioration and harm. There were 20 "GPRx v AMO(u)" unintentional discrepancies where deviating from the GP medication was considered beneficial. Hence for these discrepancies, the Cornish methodology was adapted and redefined as the following: -

Class 1* - A deviation from the GPRx record would result in minor patient benefit

Class 2* - A deviation from the GPRx record would result in patient benefit and prevent a discrepancy that has the potential to cause moderate clinical deterioration and harm.

Class 3* - A deviation from the GP record would result in patient benefit and prevent a discrepancy that has the potential to cause severe clinical deterioration and harm.

It was found that for the 20 "GPRx v AMO(u)" unintentional discrepancies that were classified as a benefit, 4/20 (20%) were class 1*, 14/20 (70%) were class 2* and 2/20 (10%) were class 3*.

The anomalous results of discrepancies between the GPRx pre-admission medication and Admission Medication Orders highlighted a possibility that some types of medications may not have been recorded accurately in the GP records. When classifying the "GPRx v AMO" discrepancies into the two categories "unintentional" or "intentional", it was presumed that the GPs had not intended to omit the record and that the intention would be for the GP to have the entire information about the patient's medication.

Examples of GPRx v AMO(u) unintentional discrepancies where deviating from the GP would have been beneficial rather than harmful is given in the table 8.

Table 8 Examples of GPRx v AMO(u) unintentional discrepancies where deviating from the GP record would have been beneficial rather than harmful

Example 1

Sodium valproate 200mg/5ml – caregiver mentioned that the patient was taking 60mg twice a day but was due to increase the dose to 80mg twice a day prior to admission – patient own drug states take as directed, GP has no record of it – and drug chart written up as 60mg twice a day. Pharmacist recommended 60mg BD.

Example 2

Sodium valproate 200mg/5ml – caregiver mentioned that the patient was taking 60mg twice a day but was due to increase the dose to 80mg twice a day prior to admission – patient own drug states take as directed, GP has no record of it – and drug chart written up as 60mg twice a day. Pharmacist recommended 60mg BD

Example 3

Methylphenidate - caregiver 10mg a day when required, GP record – Methylphenidate not mentioned, patient own drugs - 10MG at night when required - AMO prescribed as 10MG at night - pharmacist recommends 10mg at night. *"GPRx v AMO(u)" unintentional discrepancies where all sources did not agree with the pharmacist recommended therapy*

From the results, it was found that there were "GPRx v AMO(u)" unintentional discrepancies where each of the sources of information did not agree with the pharmacist recommended therapy. On some occasions the pharmacist also did not agree with what was prescribed by the hospital physician on the Admission Medication Order. This occurred in 11 of the discrepancies affecting 9 patients and a description of each discrepancy and its type of discrepancy and clinical significance provided on table 9. In summary all 11 discrepancies were resolved by pharmacists during the medication reconciliation process; 10 potential omissions were avoided and 1 dose regimen was highlighted and resolved.

PATIENT ID Age and weight	Description of "GPRx v AMO(u)" unintentional Discrepancy	Discrepancy classification (1 -3)	Type of Discrepancy
317, 9 months, 3.5 kg.	Omeprazole 10mg/5ml solution 2.5MG OD - from GP. The caregiver and PODs were both unavailable and this was not charted on the AMO, however pharmacist recommended 5MG OD MUPS	2 Moderate	Omission
342, 7 years, 10.7 kg	Midazolam buccal, caregiver has stated that they never had to give. GP confirms that patient hasn't had a supply since November 2010, nil PODs were brought in and this was not charted (No AMO order), pharmacist recommended PRN buccal - 2.5MG pre-filled syringe	3 Severe	Omission
351, 6 years, 17.6 kg	Montelukast 5mg chewable - caregiver - dissolves in water and takes OD, no POD, GP record gives 5mg OD, AMO - Singuilaire prescribed - but no dose written on the chart. Pharmacist recommends to query.	3 Severe	Direction discrepancy
405, 13 years, unknown weight	Adcal D3 take one OD by caregiver, GP record was take two OD but was last issued in August 2010, no PODs were brought in and the Adcal D3 was not written as an AMO.	2 Moderate	Omission
432, 3 years, 16.1 kg	Cetirizine - no mention by caregiver and no PODs, however GP states 5mg/5ml – 5ml OD PRN - this has not been ordered as an AMO. Pharmacist recommends that this is reviewed as patient already on chlorpheniramine	1 Minor	Omission
432, 3 years, 16.1 kg	Chlorpheniramine 2mg/5ml liquid - caregiver does not mention, no POD, GP records show 5ML MDU for anaphylaxis - not charted on AMO.	1 Minor	Omission
432, 3 years, 16.1 kg	Montelukast 10mg tablet – no mention by caregiver, no POD, GP record instructs - Crush in 10mls of water give 4mls (4mg) ON. Not charted on AMO - pharmacist recommends review.	3 Severe	Omission
435, 12 years, 41 kg	Cetirizine 1mg/ml liquid - caregiver does not mention this and nil PODs, however GP states dose of 10mg OD, not charted as AMO. Pharmacist recommends that it is not required.	1 Minor	Omission
910, 13 years, 105 kg	Risperidone 1mg/ml - caregiver gives 1.5ML BD, GP records states 1.5ML BD, POD states 1.5ML BD also, however AMO not written up. Pharmacist recommends 1ML BD	3 Severe	Omission

Table 9 Unintentional discrepancies where the pharmacistrecommendation did not match any source or the AMO

PATIENT ID Age and weight	Description of "GPRx v AMO(u)" unintentional Discrepancy	Discrepancy classification (1 -3)	Type of Discrepancy
979, 5 years, 11.4 kg	Salbutamol 100MCG inhaler - caregiver 10 puffs PRN, GP records show 1-2 puffs PRN, no PODs and not written on AMO	2 Moderate	Omission
985, 4 years, 14 kg	SALBUTAMOL - Caregiver - 2puffs BD and PRN - GP 4-5 puffs MDU, no PODs, not written up on AMO	2 Moderate	Omission

Other Anomalies

On examination of the dataset the following was observed: -

- Some drugs that were omitted from the initial drug chart, unintentional discrepancies, were as a result of the drugs not taken regularly long term but would be essential and required in an emergency. Some examples of these include midazolam buccal liquid and Epipen (adrenaline).
- Some GP records reported the patient's long term medications as "as required" or "as directed by hospital." It was hence unclear and difficult to define these as definite unintentional or intentional discrepancies.

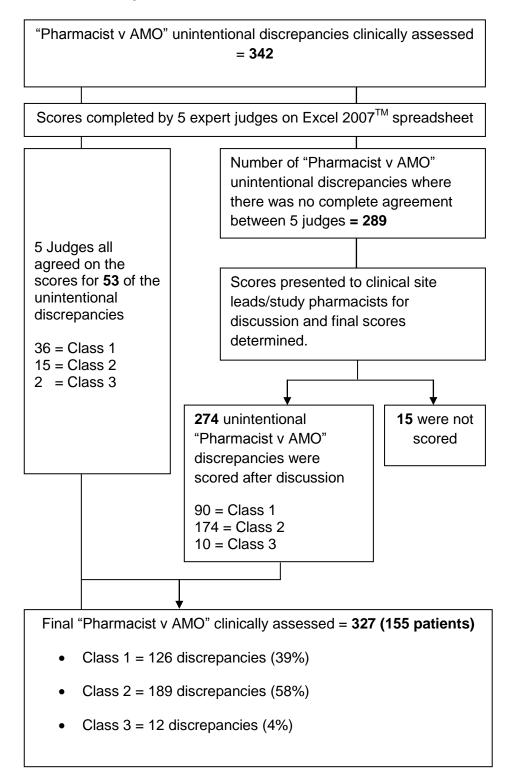
"Pharmacist v AMO(u)" unintentional discrepancies and their clinical significance

It was found from the original data that 36% (361 out of 1004) of all medication orders contained "Pharmacist v AMO" discrepancies. The overall incidence of patients with at least one "Pharmacist v AMO" discrepancy over the 5 month data collection period was 67% (164 \div 244 \times 100).

The "Pharmacist v AMO" discrepancies were then classified into intentional or unintentional based on the information collected about the AMO. The discrepancy was considered to be intentional (Pharmacist v AMO(i)) where the hospital doctor made a clear decision to change existing therapy and this disagrees with the pharmacists judgement. Discrepancies where the pharmacist and AMO disagree and the AMO prescription was an unintentional change from the GPRx were classified as unintentional. Of the 361 "Pharmacist v AMO" discrepancies 342 were classified as unintended "Pharmacist v AMO(u)" discrepancies. The 342 "Pharmacist v AMO(u)" unintended discrepancies were clinically assessed by the panel of expert judges as described in the method. The 5 judges had total consensus on scores for 53 "Pharmacist v AMO(u)" unintended discrepancies. The remainder of the Pharmacist v AMO(u)" discrepancies (289) were presented to the site leads and study pharmacists (ST, DT, KW, HH, CH) who determined the final score for each discrepancy. Figure 4 summarises the process of clinical assessment and scoring of the "Pharmacist v AMO(u)" unintentional discrepancies.

117

Figure 5 – Clinical assessment process of the 342 "Pharmacist v AMO" unintentional discrepancies



Chapter 2 Medication reconciliation upon hospital admission in children After the validation stage, there were 327 "Pharmacist v AMO(u)" unintended discrepancies affecting 155 patients. The numbers of "Pharmacist v AMO(u)" unintentional discrepancies per patient ranged from 1 to 9 discrepancies per patient (median = 2 per patient, inter-quartile range 1 - 2). Of these discrepancies, 126 (39%) were class 1, 189 were class 2 (58%) and 12 (3%) were class 3 and considered serious. In terms of the classes of discrepancies:

- 34 (21.9%) patients had Class 1 "Pharmacist v AMO(u)" unintentional discrepancies as the most serious class of discrepancy
- 111 (71.6%) patients had Class 2 "Pharmacist v AMO(u)" unintentional discrepancies as the most serious class of discrepancy
- 10 (6.5%) patients had Class 3 "Pharmacist v AMO(u)" unintentional discrepancies as the most serious class of discrepancy

The incidence of "Pharmacist v AMO" unintentional discrepancies that were either moderately severe or severe was almost 50% ($121 \div 244 \times 100 = 49.6\%$). That is, the hospital prescriber, unaware that they were making a change to the patient's pre-admission medication, have inadvertently modified the prescribed medication that, if uncorrected, could lead to moderate or severe clinical deterioration in half of patients admitted to hospital taking long term medication.

Design of the model paediatric specific medication reconciliation pathway and data collection form

From the analysis of the data from the main study and discussion with the reviewers of the proposed model medication reconciliation pathway a model medication reconciliation data collection form (Appendices F and G) was developed. This section of the results will report on the rationale behind defining the pathway and model medication reconciliation form contents.

Pathway: -

-

- The preferred pathway was to start with the parent-carer first where available, since the parent-carer was found to be the most accurate source of information available which agreed with the pharmacist's recommended therapy.
- Labelled patient own drugs or medical notes were considered as alternative starts to the pathway if the parent-carer was not available, and the data collector was asked to seek other sources until satisfied.
- The pharmacist using the pathway was prompted to ask the parentcarers if the child was taking any medications for emergency use and / or injections (as the results showed that some emergency use drugs that were long term were being omitted).
 - With regards to patient's medical notes the pathway prompted the pharmacist to look for GP letters, GP repeat prescription lists, a recent discharge letter from other hospitals, hospital outpatient clinic letters

and outpatient prescription copies. These were suggested following discussion by the study team and are thought to be important sources of data that may otherwise be overlooked These should be carefully considered by those conducting the medication reconciliation, and in particular when determining if the GP should be contacted or not.

Data collection form

- The data collection form included a column for the pharmacist to document if they recommend the patient to stop/continue/change or hold – as this would be important in the continuity of the patient's care.

Pilot data collection using the model medication reconciliation pathway and data collection form

General results and demographics

Across the four study sites medication reconciliation was conducted for 82 patients on long term medications using the pilot medication reconciliation intervention pathway and data collection form. From this 283 medications were identified and the number of medications per patient ranged from 1 – 19 (median 3, inter-quartile range 2-4). The age of the patients ranged from 18 days to 16 years of age, and 41 were female, 40 were male. One patient did not have a gender recorded. The specialities managing the patients varied and consisted of cardiology, general paediatric medicine, metabolic, gastrointestinal, neurology, neurosurgery, oncology, renal, respiratory and surgery. The majority of patients were managed by general paediatric medicine.

Choice of intervention pathway

Pharmacists were guided in respect to the 3 model medication reconciliation pathways available in this part of the study (see Appendix C).

Pharmacists conducting the data collection mainly opted for pathway A starting with the parent-carer (68/82), followed by pathway C starting with the notes (9/82), 3 did not record which pathway they used and pathway B (starting with PODs) was used twice. The patient's GP was contacted in relation to 46% (131/283) of the medications ordered, and 50% (41/82) patients. A breakdown of the number of GPs contacted per site is provided on table 10.

	Birmingham	London	Leeds	North Staffordshire
Number of GPs contacted per patient	8	13	8	12
Total number of patients	20	20	22	20
Percentage of patient GP's contacted	40%	65%	36%	60%
Number of medications where GP is used as a source	29	53	25	24
Number of medications in total	63	79	55	86
Percentage of medications requiring GP as a source	46%	67%	45%	28%

Table 10 GP usage during medication reconciliation intervention acrossthe four study sites

For the patients whose GP were not contacted, the sources used to reconcile the medications were from a variety of sources which includes: - parents, PODs, previous hospital discharge letters, medical notes, doctors notes and a neonatal unit letter.

Sources of information used during the reconciliation process

For each medication that was recorded during the medication reconciliation process, the data collector was asked to document how many sources of information they had utilised before reaching their conclusion(s). The number of sources used to reconcile each medication ranged from 1 - 5sources with most medications being reconciled using two sources (59% or 164 of 280 medications with a source recorded). There were various reasons why there were instances where only one source of information was used to reconcile an individual medication. In some instances the pharmacist carrying out the medicine reconciliation would document the same medication but different discrepant doses (reported by each source on separate rows of the data collection form) and would then finalise by indicating which dose to continue and which dose to discontinue and disregard. In one instance, the GP was the only source to mention that the patient was taking medication for Cystic Fibrosis. There were two patients where the pharmacist did not use more than one source of information to conduct the medication reconciliation and in those two cases the patient was only on one long term medication. Of the two cases, one case was a patient who was prescribed prophylactic trimethoprim liquid (parent-carer expects this to be stopped by the GP, which was accepted as accurate by the pharmacist). In the second case a parent stated that their child was using saline nasal drops purchased over the counter on a long term basis. The number of sources to reconcile each by drug as classified by BNFC chapter is provided in table 11.

		Number of sources used before pharmacist finalised medication history				
	r	1	2	3	4	5
	1 Gastrointestinal system	2	31	10	4	0
	2 Cardiovascular sysyem	1	4	0	2	2
	3 Respiratory System	3	40	15	4	0
	4 Central Nervous System	4	38	21	3	0
	5 Infection	2	12	3	0	0
	6 Endocrine system	1	15	2	0	0
	8 Malignant disease and immunosuppression	0	1	2	0	0
	9 Nutrition and blood	2	14	7	10	0
	10 Musculoskeletal and joint diseases	0	3	1	0	0
	11 Eye	0	3	2	1	0
oter	13 Skin	1	3	7	1	0
IF Chapter	14 Immunological products and vaccines	1	0	1	0	0
BNF	unknown	1	0	0	0	0
	Total	18	164	71	25	2

Table 11 Number of sources used for each drug finalised on the medication history per BNFC chapter classification

Combination and comparisons of medication discrepancies identified "GPRx v AMO, "Pharmacist v AMO" and "Intervention v AMO"

Comparison of the two methods of defining discrepancies – "GPRx v AMO" and "Pharmacist v AMO"

The different methodologies used to define medication discrepancies, "GPRx v AMO" and "Pharmacist v AMO" showed that there was more "GPRx v AMO" discrepancies (83%) compared with "Pharmacist v AMO" discrepancies (67.21%). However in terms of unintentional discrepancies, there was a higher proportion of patients with the "Pharmacy v AMO(u)" compared to the "GPRx v AMO(u)" definition. Nonetheless the proportion of the potentially serious Class 3 type unintentional discrepancies when taking the GP as the comparator was higher at 22.75% versus 3.67% when the pharmacist was taken as comparator.

	"GPRx v AMO" Discrepancy	"Pharmacist v AMO" Discrepancy
Medication orders as the denominator		
% of discrepancies in total	582/1004 = 57.96%	361/1004 = 35.96%
% of unintentional discrepancies (where deviating from the GPRx or Pharmacist recommended therapy was considered harmful)	189/1004 = 18.82%	327/1004 = 32.57%
Unintentional discrepancies as the denominator		
% discrepancies with class 1	57/189 = 30.16%	126/327 = 38.53%
% discrepancies with class 2	89/189 = 47.09%	189/327 = 57.80%
% discrepancies with class 3	43/189 = 22.75%	12/327 = 3.67%
Patients as the denominator		
% of patients with discrepancies - incidence	203/244 = 83%	164/244 = 67.21%
% of patients with unintentional discrepancies - incidence	100/244 = 40.98%	155/244 = 63.52%
Number of patients with an unintentional discrepancy as a denominator		
% of patients with class 1 (as the highest class)	22/100 = 22%	34/155 = 21.94%
% of patients with class 2 (as the highest class)	50/100 = 50%	111/155 = 71.61%
% of patients with class 3 (as the highest class)	28/100 = 28%	10/155 = 6.45%
% patients with a clinically significant moderate or severe discrepancy – incidence	78/244 = 31.97%	121/244 = 49.59%

Table 12 Summary of the discrepancy findings comparing the twomethods "GPRx v AMO" and "Pharmacist v AMO"

Comparison of the "GPRx v AMO", "Pharmacist v AMO" and "Intervention v AMO" data

It was found that the pilot intervention only prompted contact with the GP for information in 45% of the cases as opposed to the mandatory contact during the multisite study. In terms of the sources of information used to reconcile the medication ordered from the drug chart at admission, the pilot intervention data collectors used between 1 and 5 sources of information to reconcile the medication with the majority of patients using two or more and may suggest differing complexities in obtaining sufficient information before being satisfied that the medicines have been reconciled. In the previous 5 month data collection, all pharmacists had to obtain the medication history from 2-3 sources of information, and any other sources of information the pharmacist had use to reconcile the medication was not recorded. A higher proportion of discrepancies were identified by the pharmacists using the model intervention during the one month collection compared with the Pharmacist v AMO discrepancy. When the proportion of patients with a discrepancy was compared for the initial 5 month data collection and final one month data collection, the proportion of patients were similar.

128

reconciliation intervention data				
	Multisite data collection (GP V AMO discrepancies)	Multisite data collection (Pharmacist recommended therapy versus AMO)	Pilot model medication reconciliation intervention data collection	
Length of study (in Months)	5 months	1	1 month	
Number of patients in the study	244 consecutive patie	nts	82 patients convenience sample	
Number of hospital sites	4	4		
GP as a Source of information	In all cases		In 45% of cases	
Sources of information used	Between 2 – 3 from (parent-carer interview/GP/PODs)		Between 1 – 5	
Number of discrepancies out of the total number of drugs	582/1004 = 361/1004 = 57.96% 35.96%		114 out of 283 = 40.28%	
Number of unintentional discrepancies out of the total number of drugs.	189/1004 = 18.82%	327/1004 = 32.57%	64 out of 283 = 22.61%	
Number of patients with discrepancies	203/244 = 83.19%	164/244 = 67.21%	55/82 = 67.07%	
Number of patients with unintentional discrepancies	100/244 = 40.98% 155/244 = 63.52%		34/82 = 41.46%	

Table 13 Collated results of "GPRx v AMO", "Pharmacist v AMO" discrepancy from the multisite study and pilot medication reconciliation intervention data

2.3.4 Discussion

The results from this section indicate that there was no single source of information that provided a complete list of the patient's pre-admission medication. Reliable identification of the complete pre-admission medications requires triangulating the information from multiple sources. The most reliable source of information was the parent-carer (81%) followed by the GP

(70%). Other studies from Coffey et al (2009) in children described that a pharmacist medication history was taken and described the sources and gave a non-exhaustive list, but did not comment on how reliable each source of information was. Another problem that was highlighted by anomalous results was the fact that there were drugs that were omitted from the initial drug chart due to the fact that these drugs were intended to be taken long term, but on an as required basis or only during an emergency.

The intervention pilot showed that the number of sources pharmacists would use to reconcile a patients drug chart medication based on the medication history taken ranged from 1 to 5 sources, suggesting a possibility of a range of complexity amongst patients with at least one long term medication prior to discharge. This result suggests that if medication reconciliation were to be implemented in real practice, an intervention which gives guidance to the pharmacist conducting the medication reconciliation needs to be flexible and permit the pharmacist to use their clinical judgement in terms of how much depth to go into when conducting medication reconciliation. For example the intervention or guidance on medication reconciliation should help the pharmacist to discern between patients where 1) it would be suitable for the pharmacist to use one source of information to reconcile the medication history and 2) guides the pharmacist of where to look for additional information if the pharmacist is not satisfied that the patient's medication has been reconciled after observing two sources of information.

2.3.5 Conclusions

The multisite study data have shown that no single source of information is 100% reliable, (although in two isolated cases during the intervention pilot pharmacists used only one source of information to reconcile the medication for patients who were taking one long term medication). The data available from the patient's GP were not always up to date with respect to the patient's current medication. Parent-carers were identified as the most reliable source of information available but this data was also incomplete or inaccurate. Based on the pilot intervention data collection, for the purpose of establishing a drug history, the GP was required to be contacted in 45% of cases when the pharmacists were given the choice of a wider range of sources.

Parent-carers often describe medications in terms of volume of liquid or puffs of an inhaler without qualifying the dose with reference to the strength of the preparation. Hence PODs may be an invaluable additional information source, when made available, to quantify the dose. However, due to the frequency of dose changes in children, associated with weight gain the POD label may not reflect the current dose And care should be exercised when interpreting POD data.

2.4 Evaluation of the derived medication reconciliation pathway – Focus Group

2.4.1 Background

So far in the study:

- Medication discrepancies occur for children on admission to hospital in the absence of medication reconciliation.
- No single source of information can provide an accurate list of preadmission medicines.
- The pilot intervention highlighted that most pharmacists would use two sources and consult the GP in half of the occasions.

A focus group was convened to consider these issues and the proposed model medication reconciliation process.

2.4.2 Aims and objectives

The aim of the focus group was to evaluate the model medication reconciliation pathway and data collection form (see appendices C and D) in discussion with the pharmacists who were involved in the model medication reconciliation pilot data collection (chapter 2.3.2.5) and the site lead principal investigators at the four sites – Birmingham, London, North Staffordshire and Leeds.

In terms of the identified medication reconciliation service the following aspects were to be considered:

- Documentation (how medication reconciliation in children was documented prior to the implementation of the model medication reconciliation pathway and data collection form and its suitability)
- Data collection the sources used to conduct a medication reconciliation in practice
- Parent-carer interview how reliable this was as a source
- Acceptability of the intervention opinions of the _ pharmacists/investigators who piloted the model medication reconciliation pathway and data collection form on the acceptability of it in real practice. Further opinions and suggestions that were not collected during the data collection phases were gathered to refine.
- Personnel opinions and views on who should carry out the intervention, gathering views from the four sites.

2.4.3 Method

Setting, participants and data management

The evaluation took place in the form of a focus group of consisting of 8 participants consisting of hospital pharmacists and the principal investigators across the four study sites site. The hospital pharmacists were selected on the basis that they had taken part either in the design or data collection stage of the study.

The focus group had a moderator who guided the participants to discuss the following: -

- What would the participants define as admission medication reconciliation in children and what does this mean to their practice?
- What was the participant's common practice of medication reconciliation children prior to the introduction to the intervention that was piloted?
- How much time would the medication reconciliation normally take and how was this normally documented?
- The participants were invited to discuss their views on the medication reconciliation pathway and intervention that was piloted (as per section 2.3) and to suggest any additions and changes to the form
- The final discussion was over the topic of who should conduct medication reconciliation in terms of personnel for example the pharmacist or technician.

The question guide for the focus group can be found in Appendix E.

Method of data management and analysis

The focus group session was audio recorded, lasted an hour and thirty minutes. Recordings were transcribed verbatim with the details of the participants made anonymous and was transferred to NVivo version 10 to assist with the qualitative analysis. A framework analysis approach was used to qualitatively analyse the data (Ritchie and Spencer 1994). The data

were coded using an initial coding framework based on the question guide for the focus group see table 14.

Main code	Sub codes (or NVIVO nodes)
1. Paediatric medication	1.1 Best possible medication history
reconciliation definition	1.2 Best list
	1.3 Medication history
	1.4 Current medication
2. Prioritising and selection of patients for medication reconciliation	
3. Sources used for medication	3.1 Parent/caregiver/carer
reconciliation	3.2 GP
	3.3 Hospital outpatient letter
	3.4 Notes
	3.5 PODs (Patient own drugs)
4. Procedure of medication	4.1 Sources used
reconciliation (prior to	4.2 Documentation
intervention trial)	4.2 Documentation
5. Medication reconciliation	
pathway – similarities and	
differences to existing practices	
6. Medication reconciliation	6.1 Suggested additions
data collection form	6.2 Suggested changes
	6.3 Suggested removals
7. Opinions on having a paediatric specific medication reconciliation process	7.1 Comparison and contrast with adults
8. Who should carry out	9. Technician
medication reconciliation?	10. Pharmacist
	11. Other healthcare professionals
	12. Doctor

Table 14 Initial thematic coding framework

Chapter 2 Medication reconciliation upon hospital admission in children The initial 22 minutes (20%) of the transcript recording, was coded independently by two researchers CH and MW (Mariam Wahab) using the initial framework using NVivo Version 10 to assist with indexing the codes. The similarity and differences between the two coders was discussed and a final framework developed. The coding framework was used to code the rest of the transcript. The interpretation of the results from the coding of the focus group was conducted by CH and was based on the objectives of the focus group in the following areas: -

- the concept of how medication reconciliation in children is documented
- which particular sources are used
- o how reliable parent-carer interview is
- o acceptability of the intervention
- Personnel who should use the intervention

2.4.4 Results and Discussion

Paediatric medication reconciliation definition

General definition

The participants started off with their views and various definitions of what medication reconciliation was. It was defined as a process of obtaining the best list of what the patient was taking up to the point of admission:

" LD1: In my mind medicines reconciliation is trying to get the best list of what the patient was on and then reconciling it to see what they should be on now (8-9)". Other than creating a list, another process of medication reconciliation was to check the rationale of prescribing the medication against the patient's condition "BH1: - have I got the right diagnosis for the start off" and then "have I got the right drug for the diagnosis" and then "what's a reasonable dose for this child (176-177)".

The focus group participants also discussed that the initial list of medications prescribed by the hospital doctors on admission of the patient was possibly based oo "*LD1*:....the last medication intervention or the last thing that the child was actually taking (12-14)". From the start, a common theme amongst participants was uncertainty as to what constitutes the "best list" for the patient and that even finding information on what they last took was not straightforward.

The remainder of the transcript was coded into sub-themes in relation to: -

- 1) The challenges of recording an accurate patient medication history
- 2) The influence of multiple providers on a child's medication history
- 3) The GP's influence on the patient's medication history
- 4) The pharmacist's process and documentation during medication reconciliation in children; parent influence over the medication history
- 5) The variations in formulations
- Having more than one source of information to reconcile the medications.

The challenges of recording an accurate patient medication history

When discussing what medication reconciliation was, the participants felt that there was a difficultly in determining what medications a paediatric patient was on prior to admission.

"LD1: - The more we look into it, the less I know what the actual reconciliation is. Not 100% what the answer of the question is (14-15)."

In some cases the medication history was not always clear upon examining the sources of information including the patient's last medical record and this situation was described as being "grey" meaning ambiguous and not completely clear-cut. In the situations where there were grey areas and complexity with a patient's medication history, somebody had take up the responsibility to assess the patient and make a decision of what medication prescribe based on their condition from first principles.

"LD1: - Was it a drug that should have had a specific information, I'm just trying to think of, it's interesting isn't it, you know, the patient is taking this, this is what they were prescribed last, you have got a patient in front of you with a condition. So are they or aren't they being treated for it, so I suppose, is the dose they are now on acceptable, because somebody has to make a decision, and again maybe we look at it too precise in some way, maybe part of it is having an understanding of what has actually been happening and starting again (91-97)" The further challenge of taking a medication from a child with multiple care providers

Participants commented that one of the reasons behind the challenges of obtaining medication histories was because children with multiple long term conditions requiring medication were being managed by more than one health care professional.

"BH1: - 1 in 8 are getting medicines from two different prescribers and that's a huge percentage already (38-41)"

In addition to this, participants also commented that it appeared that in cases where a child was being managed by two prescribers, there were instances where there was no communication between the two.

"LD1: - So is these two separate prescribers you were finding quite a

lot of the time, and neither knew what the other was doing? (28-29)"

Another observation made by participants was that GP records did not record the patient's regular medications that were prescribed and obtained from the hospital.

"LE2: - The thing I found was that the GP records don't obviously have all the hospital prescribed medicines..... (23-26)"

The challenge of taking a medication history of a child with multiple care providers were the fact that some health care professionals were making interventions that did not involve prescribing but would alter the medication history. A participant commented that sometimes parents would consult a specialist nurse rather than the GP with a clinical problem and the nurses Chapter 2 Medication reconciliation upon hospital admission in children would intervene by putting the patient back on a medication that was for acute use and initially prescribed by a hospital doctor. An example given by the participant was that of a nurse advised the parent restart the child on a non-steroidal analgesic given historically in hospital 6 months ago.

"LE2: - ... they ring the specialist nurse, and all of a sudden they are on non-steroidal that they haven't had for the last 6 months, but they just happen to have it in their cupboard, and the nurses are like helping them like "we can go back on those", and then they come in because they are unwell, and you find out that it's not even prescribed as, from a prescription dispensed, but it had been advised by the hospital historically.... (310-315).

Primary care clinician influence on the patient's medication history

The focus group participants discussed reasons why the paediatric patient's GP record may vary with the hospital's record. One participant described a situation where a patient's prescribed medication may change after hospital discharge because of GPs adapting the medication to what is available on their prescribing system, which then may cause problems if the patient is admitted to hospital on another occasion.

NS1: - but you tend to, when you discuss with the GP, transferring the patient from primary to secondary or secondary to primary care you tend to, they tend to want to do what is on their e-prescribing system, if it's not on their computer, they don't want to do it (228-231)

Another comment made by focus group participants was an observation that some GP records did not include the medications that were hospital prescribed medications: -

LE2: "The thing I found was that the GP records don't obviously have all the hospital prescribed medicines, that was one of the big issue that came up over at ours. (23-24)"

The Pharmacist's process and documentation during medication reconciliation in children

Participants commented that the processes that junior staff from the study site hospitals were following the adult medication reconciliation guidance that was implemented by their hospital site. These procedures were based on the NICE guidance for adults admitted to hospital and suggested that the pharmacists use two sources of information to reconcile the patient's medication, one of which being the GP record. Participants were unclear whether the two sources of information suggested had to be in agreement in order to reconcile the patient's medication history and in that case whether a third source of information should be consulted. The seniors among the participants also commented that some of their junior staff would ensure that they obtained a copy of the patient's GP record as a source of information. The junior staffs were following what was recommended by the medication reconciliation training received at their trust, despite being told by the parent in some cases that the child was not on any medication prior to hospital admission.

"LD1: one of the things I've become even less and less clear about looking at the adult stuff again NICE where they it says you need two sources, is that two sources per drug, do you need two sources to clarify everything that you need to find out, or do you have two sources which give you two different lots of information , and you still need a third source or do you make up your mind, and two sources of what, and that is what makes it more grey as we have been going on (49-54)."

"LE2 – It is interesting you say that, we have a lot of our junior staff do the adults medicines reconciliation accreditation in the Trust which is based on NICE, and we have had them rotate all rotate this week , and its quite interesting now that they've come to a paeds ward, they are like "I need a GP printout, so I get a second source to the parent" so the parent says they are on nothing, their medical history is nil you don't have to contact the GP, but it's so drummed into them that it is two sources, and if the two sources don't match they just panic. (55-61)"

The participants also commented on the role hospital pharmacists played in reconciliation. They acknowledged that the hospital doctor, who wrote the initial drug chart upon admission, also did a form of medication reconciliation; however this might not be as thorough as the process of reconciliation undertaken by a pharmacist. The following extracts below illustrate some of the views of the participants: -

142

"BH1: I think there's a potential for a difference between the pharmacy view over these things to a medical view, so um, I think maybe the pharmacy team, we are members of that, we tend to be a little bit more specific then the medics may be in some occasions, so we are saying we want this drug in this formulation at this dose at this time of the day, absolutely clear, but when you have direct clinical responsibility for this child you would be thinking "have I got the right diagnosis for the start off" and then "have I got the right drug for the diagnosis" and then ok "what's a reasonable dose for this child" and I would be interested to find out how often prescribers are saying to carers "it's ok if you change the dose because of this" you know rather than just exactly what's written on the form, so to a degree that leads to what's the quality of the information source that we are getting with this..... (171-182)"

"LD1 although in some ways, pharmacists....., we meddle too much around, going on that adults have the same dose whether they weight 40 or 100kilos we have those conversations, but in paeds go totally precise with three decimal points on something, and um yet most drugs have a wide therapeutic range in kids, and it's probably somewhere between the medics and us, is the best place to be, and the combination is fantastic because I think that does work, but I wouldn't say we're particularly right and they are particular wrong, and I think it is probably the amalgamation of the two which is probably somewhere along the middle. NS1: - I think we take the dosage that's

Chapter 2 Medication reconciliation upon hospital admission in children prescribed alongside the patient, you know, whether they are adolescent and on tablets etc, and we interpret the prescription in that way don't we, so we say you want ranitidine 50mg in a ml liquid or you want MUPS or whatever, I guess that's where the prescribers leave off and we pick up don't we, (188-199).

Parent influence over the medication history

The parent-carer was highlighted as an important source of information, although not 100 per cent reliable. For example, they were important in identifying which medicines were prescribed by the GP and which other care providers were involved. The focus group highlighted certain points regarding the reliability of the information provided by the parent: -

- Parental knowledge of medications some parents did not know the concentrations of the medications
- Understanding the dosage the participants gave examples of situations where parents would only give the child the volume of medication which was prescribed, some examples of situations the participants recalled is given below: -

"BH3: - We often get phone calls from the dispensary from worried parents, um saying "we've come to community and we used to be on 3mls and now we are on 6mls, what's going on?" and then you have to scroll through the PMR and then find the strength, do the calculation and say "yes that's the same".... (221-225)"

• Adapting the prescribed dose

Participants in the focus group posed the question of whether the best list of what the patient was taking prior to hospital admission during a medication reconciliation was: - *"LD1: - is it their last hospital appointment, is it the last GP appointment, or is it what they changed themselves halfway through any of those bits and pieces?(10-12)."*

There were various reasons given of why a dose was given differently to what was prescribed and examples that were given were, "*LE2: - in the last clinic they changed that dose (113)*", "... *they haven't had any fits recently, hence we have reduced the dose... (107-108)*" or "parents were telling us exactly what they wanted us to do..... were trying to convince us to give drug X ".

The appropriateness of whether such a change by the parent-carer was also discussed with a participant highlighting that it depended on the drug.

Variations in formulations across care settings

The participants discussed the issue of variations in formulations for children. This included the use of "specials" formulations and different care providers swapping formulations. Either presented a medication safety risk and potential cause of errors as patients move from one care setting to another.

"LE2 but recently we have had quite a few acute admissions to hospitals because of the poor quality of the specials, there are two in hospital with anti-epileptics, where a special is compromised and the GP has started it, (140-142)"

"NS1: and it does come back down to when you do your med rec, having to, because you may have discharged them with say "they were on omeprazole liquid for an NG tube" you may have discharged them on 10mg/5ml but somewhere along the lines there's been a switch to 20mg/5ml or whatever other formulation they happen to want to issue, and so there's this potential for confusion for the parent, but then as they say when they come back.... (166-170)"

BH3: - We often get phone calls from worried parents, um saying "we've come to community and we used to be on 3mls and now we are on 6mls, what's going on" and then you have to scroll through the PMR and then find the strength do the calculation and say "yes that's the same" and it's just reassurance you are giving them and that's what they are looking for (221-225)."

Consistency

"BH2: Um and just coming back to the point about specials, it's caused more errors in the prescribing of medicines on admission for example omeprazole they write 2.5ml BD, just omeprazole, but I know that there's so many varieties of omeprazole formulations. I find out the patient is on 20mg/5ml, and we keep 10mg/5ml stock, they have given the wrong dose over a couple of days over the weekend, um, but then you think about the intervention itself, has that caused a detriment to the patient, they have not complained the reflux has not got worse. (271-277)"

One particular participant stated that in their practice in hospital they would usually crush tablets rather than supply a special formulation due to issues with stability.

"LE2: - We have quite a few, where they have been discharged with on say tablets and you crush them, as we avoid specials, whereas the GP had prescribed specials, and basically we don't like specials because of the stability, this that and the other, so there was a pharmaceutical reason why we didn't do it, (130-133)."

Participants also discussed that in some cases, special formulations were started in the community by the GP or community pharmacist. Some participants suggested that this decision may have been a result of misinterpretation of the information provided by hospital discharge letter or hospital prescription. There was also a cost association with it: -

"NS1 – We've had quite a few with ranitidine liquid, where the community pharmacies have just interpreted your 15mg of ranitidine as a special, and made a 15mg/5ml liquid. I've taken it up with the PCT (152-154)."

Requiring more than one source of medication to complete the reconciliation

The participants felt that more than one source was required for reconciling a patient's admission medication record against the drug history. Suggested reasons behind the requirement were the completeness of the sources of information that were being retrieved as one particular source may not have

had all the information about the patient's medication. Examples of the discussion from the focus group are given below:-

"LE1 – Quite a lot of the parents don't always know what the concentrations of the liquids are which is why you need to go back to the GP to find out (34-35)."

"NS1 – And at what point does, I mean you have a POD but a POD without a direction, so you've got that indication that the patient is on meds but it is just take as directed, and that becomes.... You know, you have got two sources of information that tells you the patient is on it, but they don't clarify (62-68)".

"LD1 – So is this two separate prescribers you were finding a quite a lot of the time, and neither knew what the other was doing? NS1: -Which is really worrying? LE2: - Yes; LE1: which demonstrates why you need more than one source."

Prioritising and selection of patients for medication reconciliation

The participants discussed how they prioritised their time and identify patients who required more time to conduct medication reconciliation for example patients who had a long medication history. One participant *BH2* conducted medication reconciliation *"every day for every patient"* and that it was more subconscious as part of the participant's practice. Another participant LE1 expressed that medication reconciliation was done as part of a medication review with three different levels of review with 1 being the basic dispensary level and level 2 and 3 being the more complex. Apart from

the two comments and despite prompting from the moderator, this area was not discussed by the focus group participants in any further.

The medication history sources available and its validity for use in medication reconciliation

Participants from the focus group made the following comments regarding the validity of sources of information used to obtain the medication history for a child.

Last GP appointment, Last hospital appointment, Last medical record or last recorded meeting

The focus group participants from the very start, referred to obtaining the last medication record and raised the question of what form it would be in, and the question initially raised with regards to this "document" source was:-

"LD1:is it their last hospital appointment, is it the last GP appointment or is it what they changed themselves or halfway through any of those bits and pieces (10-12)."

Subsequent participants have added in conflicting comments about the vaguely described "documented last medical record". One participant gave an opinion that in a lot of the circumstances the last recorded meeting and the parent's administration of the medications would "marry up (17-18)" and however another participant made a comment that it was "not always clear (19-21)".

Parent as a standalone source and question of the validity of the information

During the discussion regarding the definition of medication reconciliation, all participants considered speaking to the parent-carer as an important and essential starting point. Parents were considered a good source of information, and starting point to find out where to look for further information.

"LE2: - There were loads of patients where actually, if you hadn't spoken to the parent-carer for example you wouldn't have the list complete anyway. (24-26)."

Participants also raised concerns about the information provided from the parents as it was acknowledged that parents sometimes adapt the treatment without being advised to by a healthcare professional and give the medications to their child in a different way. For some medicines, adapting the treatment seemed reasonable, however for certain drugs it was not considered reasonable to vary the dose.

"BH3: The parent would say "no, this dose, the doctors given us this, but we have reduced this and now that works fine and that's what we do", then, we can go with one parent who is with the child all the time, who see the child more than anyone else, (98-100)."

"NS1: It depends on the drug doesn't it, and what has been treated. If its constipation, you know, actually adjusting the dose by the parent is probably a reasonable, you know or analgesia or something to help them sleep, you know but it is as you say (102-104)."

Another reason why participants questioned the validity of using the parent's information to reconcile the medication was because some parents were not aware of the concentrations of the formulations used and this was when the participants may contact the GP or community pharmacist to confirm the concentration of the formulations.

"BH3: - but then again it's the strengths, sorting out the strength from the parents always, when you ask them you know, how much does the child take, they will always say, "they take this many mls", and when you ask them for the milligrams, they don't really know, and you are chasing that up as well. (87-90)."

There was one participant who highlighted that there may be a minority of cases where parents may try and manipulate healthcare professionals to prescribe their child what they think their child should be on and taking the opportunity to do so at a transition in care scenario.

Patient Own Drugs

The pharmacist focus group participants felt that patient own drugs that patients would bring into the hospital at admission were useful however sometimes the PODs did not provide the person taking the medication history and reconciliation with sufficient information. PODs were considered useful in determining the form of the drug e.g. if the patient had the medication as a liquid as opposed to crushed tablets. The participants hence would use PODs as second line and would generally require confirmation that the PODs belonged to the parents.

"NS1: I wouldn't routinely ring the GP, and I've always followed the path that we've came up with here, so we'd always use the parent as the first line source and then the PODs as the second line, erm and obviously when the answers weren't you know, clear at the end of that process, then I would start digging deeper into the notes and or clinic letter and the GP would usually be my last resort (353-356)"

Procedure of medication reconciliation (prior to intervention)

The participants were asked about the procedure they would normally use in practice while carrying out medication, the guidelines they would follow, the sources they used, the time it took them and also how they would normally document their reconciliations.

Guidance followed by pharmacists conducting medication reconciliation in children

One participant who came from an adult hospital pharmacy background commented that they would conduct the medication reconciliation in a similar way to how they were trained in adults and did not find anything different although they had to do "extra bits": -

"BH2:So when I came to the children's hospital, I automatically did med recs, so when the study came about, the processes that I was doing for the study, I was already doing, and I didn't find anything I was doing different, and maybe I was doing things a bit extra, like getting two sources of information, but I don't think I was doing anything better in the sense of my clinical practice, so I thought that I do implement med recs in my everyday practice for every patient I see

on the ward, and it does help to highlight missed doses or medicines especially PRN medications, you may ask a patient "are you on any regular medicines," they might say "no" right then and I put something else in "are you taking any inhalers eye drops" and suddenly that opens another barrier they don't assume that eye drop or inhalers is a regular medicine, and then you go into "what are they on?" they are on "becotide and salbutamol" so you are already hitting on the fact that they have missed that off on the admission (259-269)"

Another participant explained that junior pharmacists at their trust were trained on the adults' medication reconciliation accreditation which was based on the NICE guidance. The participant found that when the junior staff rotated to paediatric settings they ran into problems when they tried to follow the adult medication reconciliation procedure.

"LE2 – It is interesting you say that, we have a lot of our junior staff do the adults medicines reconciliation accreditation in the Trust which is based on NICE, and we have had them rotate all rotate this week , and its quite interesting now that they've come to a paeds ward, they are like "I need a GP printout, so I get a second source to the parent" so the parent says they are on nothing, their medical history is nil you don't have to contact the GP, but it's so drummed into them that it is two sources, and if the two sources don't match they just panic (55-61)"

The sources of information that were used to conduct medication reconciliation

During the discussion regarding the procedure for medication reconciliation prior to the intervention, the participants felt that starting the process of medication reconciliation with the parent would help identify the where to look for the complete medication record (including the medication, formulation, dose and current directions).

One participant, when asked whether the sources of information that he would consult when taking a medication history for a child the same as the sources of information he would consult for adults, for example contacting the GP. The participant responded that it was not that straightforward in the case of children. The participant found that sometimes children were on medications that the GPs may not be prescribing. With the medications that were prescribed and supplied for the child in primary care via the community, at times the information on the medication and the way it was labelled did not reflect the dose that the patient was taking at the time due to possible undocumented dose changes. The participant said that in the end when a decision needed to be made on what the child was meant to be on, clarification, the participant was required to contact the hospital consultants who looked after the patient. The account made by the participant is as follows: -

"BH2: - It was pretty much the same, the only difference that um, was when we talked about the two prescriber issue earlier, and um a lot of the GPs were not, especially the old patients who were taking unusual

medicines the GP wouldn't be prescribing it, so they would be getting it from the consultant, they wouldn't know about it, so it won't be in the GP letter or admission note, but the parent would know what they are on, so you need to get the consultants name and you follow it through in terms of consultant letter, to find out what regular medicines they are on. And also about the doses, um, the community pharmacy labels the medicine as it is on the prescription, but the parent says that they take a different dose to that, because the consultant has called them up to say change the dose, but the community pharmacy cannot change that, because they don't have a physical prescription to do that. So they have been labelling that medicine for over a year incorrectly because they don't have an official document to change the dose. (284-295)."

Time taken to conduct medication reconciliation in a child in practice

When participants commented on the time it took to conduct medication reconciliation, there were varied responses. However it was indicated by one participant that for patients who were not on any regular medications it would take around 2 minutes: -

"NS1: - but there are the few patients, whereby a simple 2 minute conversation with mum to ascertain that they weren't on anything (361-363)"

Another participant felt that there was a time range in terms of the time required to complete the reconciliation, and the time taken to contact the GP and obtain the information contributed to this range.

"BH4: - In terms of the time taken, it could range from anything from 10 minutes, if you are lucky, if the mum's there, you can get through to the GP first time, you can get the fax sent over, that could be 10 minutes or it could be an hour up to, if mum's not there if dad's not there, you try to ring the GP, or you don't have the number for the GP, or its engaged, or please ring back after this time, it could range from anything really in terms of the time it takes. (347-351)"

Documentation of the medication reconciliation in normal practice

When the participants discussed the ways in which they were normally documenting medication reconciliation, many various ways were discussed which included the following: -

- Documenting the changes in the inpatient notes
- Having a designated section at the back of the drug chart although this was only seen as for pharmacy use
- Making appropriate endorsements on the drug chart

Comments were also made on why medication reconciliation recommendations were documented in various places. One participant's pointed out that they would document recommendations as written endorsements on the drug chart. The reasons behind such documentation were due to the fact that the doctors would take notice if it was visible on the prescribed medicines section of the drug chart rather than written on another section of the patient's notes.

"BH2: - That would depend on them reading it, and I won't lie to you, 9 times out of 10, they won't read it and because when I was doing the drug prescribing elsewhere we had an option to do a review note, and it was really easy, we would put everything down, without looking messy, when I came to the paediatric hospital it was all paper drug charts, so I didn't want to get out of that practice, so I do review notes on the drug chart, as brief as possible, there's like a small section that says special instructions, and if I'm not sure I put please review dose, mum says this, but this says that, and 9 times out of 10 that is reviewed, and it does get amended. So I know for a fact that they are going to read that at some point. (501-508)"

Medication reconciliation pathway – similarities and differences to existing practices

When the focus group participants were asked about the similarities and differences of the medication reconciliation pathway to existing practice, one respondent made the comment that they would not routinely call up the GP.

"NS1: I wouldn't routinely ring the GP, and I've always followed the path that we've came up with here, so we'd always use the parent as the first line source and then the PODs as the second line, erm and obviously when the answers weren't you know, clear at the end of that process, then I would start digging deeper into the notes and or clinic letter and the GP would usually be my last resort, erm and that would normally be to specify your formulation, and I'd usually and say to the parents, "where do you, get it from, last?" because that gives

you an indication of you know if it was from us, it usually narrows it down, but once you've gone to the GP, so I would either go to the community pharmacy or the GP, so the time depends on the patient doesn't it? (353-361)"

Medication reconciliation data collection form

When participants were invited to comment on the data collection form (appendix D), the following suggestions of changes were made: -

- Sections F, G and H (Last taken by, pharmacist recommendation (Stop/Hold and change and Notes), should be merged into one column
- Another suggestion was made for column G pharmacist recommendation to be the last column
- Column A the medication and dosage form was suggested to be two separate columns rather than one column

One participant also commented that there was difficulty in knowing what to put in the "last taken by patient" as this term was considered ambiguous without further information.

Opinions on having paediatric specific medication reconciliation

The participants in general felt that there should be paediatric specific medication reconciliation. One participant *LD1* felt that the "adults need to use the children's one (957-958)" in terms of the medication reconciliation procedures. The following elaboration by the participant was made in support of the participant's view: -

"LD1: I think we think about the medicine itself probably more generally more than adults. You come across its been many years since I've done adults, I, you know I think the pharmaceutics side is probably thought about more in paeds, then it is in adults in terms of formulations and that sort of thing, and therefore we are stressing those more, whereas the forms that have generally been created, and I have seen a few that have been for adults, generally don't have those sorts of things, so it's not a problem for them to use ours but it is a problem for us to use them (972-978)."

Apart from having a paediatric specific medication reconciliation process, a participant highlighted that the training of how to carry out medication reconciliation in may be different depending on speciality or paediatrics: -

"LE1: I think you do need different training depending on, I don't know whether it comes down to adults or paeds or whether it's different types of parents you have, so we probably do a drug history totally different on a liver transplant patient then we would on an elderly adult for example so whether it comes down to more erm – choosing the right method for that patient rather than defining whether they are a child or an adult."

Who should carry out medication reconciliation?

In the concluding part of the focus group, the participants were asked the question of "who should carry out medication reconciliation?" Three possible healthcare professions were discussed and compared. The idea of what the

role of technicians and pre-registration pharmacists had and whether they should do the complete reconciliation process rather than the pharmacist was discussed. A second idea that was discussed was whether doctors or pharmacists on the wards should do the reconciliation.

During the discussion of the role and profession who should be responsible for medication reconciliation, participants pointed out that the process of "Obtaining the Drug History" and subsequently "reconciling the drug chart medicines against the drug history" were "two different things". The general discussion and view of the participants based on what was their current practice, was that technicians and pre-registration pharmacy students would generally do the medication history to obtain the information and the pharmacist would "interpret" the information gathered to make a clinical judgement which exceeds the training that pharmacy technicians currently receive.

Examples of the views given are illustrated in the following selected extract from the focus group: -

"LE2: But isn't it also part of what LE1 was saying, that drug history and med rec are two different things, so for us we would have erm our technician or Pre-Reg do the drug history, but you would still need a pharmacist to do the Meds rec, (NS1: yeh), to confirm it with this that and the other. You can obviously start training them, but, its where you've got the two signatures, that's how we separate the two processes really, its so that your technician can go and get the drug history, but you say using the clinical (NS1: clinical yep) interpretation

and in some ways I think that's how you've got your two signatures boxes. (900-906)"

A participant gave a view point and suggestion that pharmacists were not actually reconciling but actually checking the medication reconciliation conducted by the doctor which what was written on the initial drug chart but possibly not conducting the reconciliation up to an acceptable standard. Although there was this view, some participants expressed their views that pharmacist should be doing the medication reconciliation based on the quality. One participant highlighted however that this may be a biased view as a participant commented that if doctors were part of the focus group participants, they would have argued that theirs were sufficient.

2.4.5 Conclusion

From the focus group, participants' opinions on medication reconciliation in children were: -

- Medication reconciliation in children was different from adults and required an alternative approach.
- Children are often seen by more than one healthcare professional, not just the GP outside that of a hospital setting.
- A child's medication reconciliation should be conducted using more than one source and that the parents were useful in providing most, but not all, the information and could signpost the pharmacist as to where to look for further details.

- Participants also stated that parents often referred to their children's liquid medicines in volume units, which made the patient own drugs valuable in identify a dose in cases.
- With regards to sources of information, it was commented that the sources of information were sometimes difficult to find and locate.
- Who should conduct medication reconciliation was discussed. The role of doctors, pharmacists, pharmacy technicians, and pre-registration pharmacists were considered. The participants concluded that medication reconciliation on admission was actually two separate processes. The initial process was fact gathering, suitable for completion by technicians and pre-registration pharmacists. The second process involves interpretation of data and final conclusions and this is best performed by a pharmacist.

2.5 The feasibility of a randomised control trial for an admissions reconciliation intervention for children – a survey of paediatric pharmacists on current practice of medication reconciliation

2.5.1 Background and purpose

From the previous chapters, it has been found that there were only limited studies and evidence in the UK that looked at medication discrepancies that occur across the transitions in care (chapter 1), with sections 2.1 - 2.4 illustrating that medication discrepancies do occur during data collection of patient's medication history, discrepancies and clinical assessment potential clinical harm of those found to be unintentional across four UK hospitals. The focus group highlighted that medication reconciliation was being

Chapter 2 Medication reconciliation upon hospital admission in children conducted in children in these hospitals and thus it would be difficult to evaluate the effect of the complex medication reconciliation intervention versus routine care. If such a trial were to occur, the results may not show the true effect or benefit of the intervention.

The purpose of this section of the chapter was to survey paediatric pharmacists across the UK to ascertain the current policies, practices and levels of MR services for children admitted to NHS hospitals in the UK. If other hospital paediatric wards already have practice and pharmacist conducted medication reconciliation services in place, this would demonstrate that a randomised controlled trial would not be feasible.

2.5.2 Methods

An online survey (Survey Monkey®) was used to ascertain if and how MR was being practiced in UK hospitals. The survey was sent to members of the Neonatal and Paediatric Pharmacists Group (NPPG), a group for paediatric pharmacists/technicians with an interest in paediatric/neonatal pharmacy.

The survey consisted of a series of open and closed questions designed to elicit information around three main themes (see table 1 for summary table):

- 1) presence of a MR policy, and its application to children
- 2) actual practice of MR in children
 - Criteria for conducting MR
 - Timeliness and time taken
 - Sources of information used
 - Professional responsible

3) need for MR in children

Questions relating to the actual practice of MR were only available to those respondents who indicated the presence of a MR policy at their organisation.

The list of paediatric pharmacists was obtained with permission from the Neonatal and Paediatric Pharmacists Group NPPG administrative office, and out of the 255 members, 187 hospital pharmacists were identified. One hundred hospitals were represented, so one randomly selected pharmacist from each hospital was contacted via email in April 2011. Reminder emails were sent to all respondents 1 and 4 weeks after the initial email was sent. In three cases, the initial survey respondent was unavailable as the mail was returned, and in one case, another pharmacist from the same hospital was identified instead. Hence, in total 98 hospitals were surveyed. Anonymous responses were collected by the online programme and the results were exported to an excel spreadsheet. Ethical approval was obtained from the School of Pharmacy, University of London Ethics Committee.

2.5.3 Results

Responses were received from 64 of the 98 NPPG pharmacists contacted, resulting in a 65% response rate.

Policy and application to children

The pharmacists were asked if there was a policy for MR on admission in their organisation and 83% (53/64) responded that they had of which 42% (22/53) had a policy that included children. When asked if MR was carried

Chapter 2 Medication reconciliation upon hospital admission in children out for children, 67% (43/64) did, 9% (6/64) didn't, 16% (10/64) had no policy in place (and were unable to respond to this part of the survey) and 8% (5/64) didn't respond. Of the 6 that did not carry out MR in children – the survey asked why MR was not carried out and five responses were given of which four (80%) indicated that they carried out MR but only for selected children.

MR was carried out on discharge by 33% (21/64) of respondents.

Practice of MR

Source of information

Respondents were asked to rank five sources of information they would use to carry out MR and were able to include details of other sources. Information from the carer was used most frequently 84% (36/43), followed by patient's own medication 56% (24/43), the patient 26% (11/43), previous hospital records 21% (9/43) and lastly the General Practitioner (GP) 5% (2/43). Other sources of information provided by respondents were, the community pharmacist, previous discharge letter, electronic dispensing records, respite care facilities, care homes and transfer letters.

Timeliness and time taken

39% (17/43) of respondents aimed to complete MR within 24 hours, 35% (15/43) between 24 – 48 hours, and 14% (6/43) within 72 hours. There was great variation in response with regards to the average time spent on MR in

children per patient, ranging from 1 to 45 minutes; the mode response was 10-15 minutes on average.

Need for medication reconciliation

All respondents were asked if the NICE guidance should be expanded to include children less than 16 years, 85% (54/64) agreed, 2% (1/64) disagreed and 14% (9/64) didn't respond. When they were asked why certain trusts may not consider MR in children to be a priority: 9% (9/64) chose that there was no evidence, 33% (21/64) selected that it was too time consuming and 78% (50/64) selected that it was due to competing priorities for limited resources. The respondents were invited to briefly describe a recent situation which posed a potential threat of harm to hospital inpatients as a result of the absence of MR in children. There were 40/64 responses, of which 37 described specific potential situations. Two examples of cases illustrating potential harm when medicines reconciliation was absent are given below: -

Case 1 Miscommunication with documentation

'A GP letter gave a dose of .5mg TDS in a hand written letter. The child was under a consultant at the district general hospital and Tertiary Centre. The dose of this antiepileptic was in the process of being weaned and on admission was down to once a day (OD). Child prescribed 5mg TDS as copied from GP letter but should have been 500 micrograms OD. GP had used a dot rather than written 0.5mg. Current dose had not been confirmed with parents.'

Case 2 Dosing volume versus units prescribing error

'A nurse requested clobazam mixture for a child (1mg in 1ml strength) as child prescribed 1.5 mls bd. Wanted the standard strength that we kept. I checked patients notes and with relative and confirmed that a supply of 2mg in 1ml was usually obtained from community pharmacy. Potentially a 50% reduction in dose could have occurred if the pharmacist had not intervened. This also happens a lot with children prescribed phenobarbitone in mls rather than mg.'

2.5.4 Discussion

The results indicated that medication reconciliation upon hospital admission in children was being carried out by 67% of the pharmacists surveyed despite only 34% of pharmacists working in hospitals with a policy which included children. Most respondents wanted the NICE guidance amended to include children. There were many examples of potential patient harm in the absence of medication reconciliation service, the majority of which were dosing errors, omission errors and involving antiepileptic drugs.

2.5.5 Limitations

Paediatric pharmacist members of NPPG were the only pharmacist group that were targeted by the survey, which is just one healthcare profession who are involved in the medication reconciliation process. Another limitation was that the survey was not made available to non-members of the NPPG who

were paediatric pharmacists or rotation staff who have worked in paediatrics for a short period of time.

2.5.6 Conclusion

In conclusion, the survey shows that medication reconciliation in children is being carried out inconsistently by pharmacists and a majority of those surveyed would like the NICE guidance expanded to include children.

2.6 Summary of project findings, implications for practice, limitations and recommendations

2.6.1 Summarised project findings

The main multisite study has demonstrated that: -

- The paediatric population across 4 UK hospitals experience discrepancies in their initial drug charts (AMOs) that are written up at admission by the hospital doctors.
- A proportion of the "GPRx v AMO" unintentional discrepancies are clinically significant and can lead to harm if left unchanged, supporting the need for medication reconciliation services.
- Anomalous results show that the GP record was not the most reliable source of information or representation of the patient medication history, whereas the parent-carer was the most reliable, but incomplete, source.
- Many sources of information may be required to reconcile the patient's drug chart and that the pharmacist recommended therapy, based on these sources, was considered to be the best possible representation of the pre-admission medication.

The intervention study demonstrated that: -

- In practice GPs were not always consulted the clinical pharmacists when obtaining a medication history and reconciling the medication.
- With the exception of two cases, all patients' medicines were reconciled using at least two sources of information and there were

also cases where 5 sources of information were needed before the pharmacist completed the reconciliation. The range of sources required to reconcile a paediatric patient's medication history suggests that the service needs this patient group varies and pharmacists need to discern between cases where one or two sources of information will be sufficient and would need guidance on what to do and where to look for further information if they are still not satisfied that the medication reconciliation is complete after using two sources of information.

The focus group concurred with this view that one source of information would not provide the complete information on a paediatric patient's history and that the process of obtaining a medication history from a child differed from the adult model.

The survey conducted on paediatric hospital pharmacists showed that across the country, medication reconciliation was being conducted in children in their settings and it would be difficult evaluate a medication reconciliation intervention using a two armed open labelled routine care versus medication reconciliation randomised controlled trial approach.

2.6.2 Study Limitations

The study covered four geographical regions in England and two of these sites were major children's hospitals. Only children who were on long term medications were included in the study. This study did not include patients who were admitted and subsequently discharge out of hours before being reviewed by the pharmacy team and the study design did not set out to

stratify and ensure that all specialities of paediatrics were represented proportionately.

The study was pharmacist led and may be considered to have justified a service that was taking place in clinical pharmacy amongst the paediatric pharmacists, but is not part of the national guidelines. Hence, this study may be biased, although the issue of poor medicine reconciliation currently is evidence based.

The study scope did not cover the aspect of whether patients with more than one condition and with polypharmacy would be at increased risk of discrepancies. The study also did not explore the issue of patient outliers and whether this circumstance influences omissions outside of the specialty the patient is located within.

2.6.3 Implications and importance for clinical practice and policy

This study supports the view that medication reconciliation is required for paediatric patients in order to reduce potential clinical harm as a result of discrepancies that occur across the interfaces of care. This service should be part of the clinical ward pharmacist's role despite there being no national guideline policy that covers children.

The main multisite study has demonstrated that there are clinically significant discrepancies that occur across the four English study sites and these findings should be considered generalisable to other paediatric settings. Without the use of medication reconciliation, paediatric patients are at clinical risk of unintended medication changes. NICE should reconsider its existing

guidance and now include children within the expectations of medication reconciliation services.

This study provides additional evidence of the clinical importance of performing medication reconciliation on admission of children to hospital and provides a model pathway to perform this service. The pathway was successful used in all 4 study sites. However, this study was not designed to identify which staff groups can perform this service. Throughout this study pharmacists were used to undertake and record the reconciliation and to make discrepancies know to prescribers for resolution. After completing over 300 paediatric medication reconciliations under study conditions across 4 sites, the study team held the opinion that pharmacists are well placed to perform this role and that the data collection part of the pathway is suitable to delegate to trained pharmacy ward technicians. Further research is required to identify if these opinions are supported by evidence.

2.6.4 Suggested further studies and actions

The study was an observational study which was aimed at identifying the occurrence of medication discrepancies in children. Suggestions of further studies would be: -

- To carry out an economic evaluation on the medication reconciliation intervention and model the cost effectiveness of this service.
- To conduct observational studies at other interfaces of care, for example transfer, discharge and post hospital discharge.

- To design a handbook on how to conduct medication reconciliation in children admitted into hospital as an education tool and guidance for pharmacists and student healthcare professionals in training.
- To identify if hospital doctors responsible for prescribing on admission agree with the recommendations of this study.
- To run the same study, but stratifying the patients into admission ward speciality to identify 'outlier' effects on medication omissions.

3.1 Aims and objectives

3.1.1 Aim

The aims of chapter 3 were to assess primarily how accurate were hospital discharge letters when initially written up by the discharging doctor prior to hospital pharmacist screening and amendments and the potential severity of these errors if the pharmacist amendments were not made. Secondary aims were to find out how timely GPs would receive the discharge letters and to explore the procedure that GP surgeries have for reconciling the medication based on changes made at hospital.

The care quality commission has reported on quality, timeliness of discharge medication provision and also surveyed GPs on who conducts medication reconciliation in their practice (CQC report 2009), however the findings were not paediatric specific. Hence this chapter aims to address this knowledge gap.

3.1.2 Objectives

A prospective two stage study was conducted to:

 identify discharge letter errors by comparing records and also by rating each error identified using a validated severity assessment tool for medication errors and to assess the timeliness by contacting GP surgeries 72 hours post hospital discharge to confirm receipt collection

2) GP surgeries of paediatric patients discharged were interviewed two weeks post hospital discharge to see how the information in the discharge letter would be used and also to gain insight into how the patient would be reviewed post discharge.

3.2 Methods

3.2.1 Stage 1 Hospital Discharge prospective review of drug charts

Setting

All wards using electronically generated discharge medication letters at a London Paediatric Hospital providing both tertiary care Nationally across England and local secondary care for patients in South London.

Study design

Prospective review of the hospital discharge procedure from the final drug chart to the final copy of the hospital discharge letter.

The review of 501 electronically generated discharge medication orders from 142 paediatric patients discharged at a London teaching hospital over a 5 week period between March – April 2011, were examined prospectively and the following records were compared: -

- the final in-patient drug chart at the point of discharge, the finalised medication list at discharge
- printed signed copy of the initial To Take Away (TTA) discharge summary produced electronically by the physician

- 3) the pharmacist's amendments on the initial TTA that were hand written
- the final electronic patient discharge summary record (the copy going out to the GP surgery with the parent/patient being provided with a copy to take home)
- 5) The patients final take home medication from the hospital

Discrepancies between the physician's order 2) and pharmacist's change(s) 3) were compared with two types of failures – "failure to make a required change" and "change where none was required".

Severity assessment of discrepancies

The discrepancies between the initial prescribed discharge medications and the pharmacist's amendments were clinically assessed for severity using a validated methodology by Dean and Barber (1999). Five healthcare professionals consisting of 1) a consultant paediatrician (JJ), 2) a consultant pharmacist in paediatrics (ST), 3) a lead pharmacist in medication safety (YJ), 4) a senior lecturer in pharmacy practice (MG), and 5) a research pharmacist (CH) were sent an excel spreadsheet of discrepancies and asked to score each discrepancy according to severity using a visual analogue scale. The visual analogue scale was a 10 point scale ranging from 0 which represented no harm and 10 which represented death. The judges marked on the scale how severe they thought each discrepancy would be. A mean score average from the 5 judges was calculated for each discrepancy. The

scores were then translated to severity using the following criteria: for mean scores below 3, this would represent minor harm, for scores between 3 and 7 would represent moderate harm and any score above 7 would represent severe harm (Dean 1993).

Timeliness of discharge letter reaching the GP

The GP surgeries of the 142 patients were contacted 72 hours post hospital discharge and the reception staff were asked if the discharge letter had been received.

3.2.2 Stage 2 GP receipt and reconciliation process

Following the first stage, GP surgeries of patients discharged from the hospital during July – August 2011 were contacted 2 weeks after they were discharged and administrative staff was interviewed by telephone on their procedures for reviewing medication changes and updating their records after discharge. An interview schedule was developed by a research pharmacist (CH) and had been commented on by a consultant pharmacist (ST), medication safety lead pharmacist (YJ) and also at local Primary Care Trust (PCT) General Practitioner and was subsequently amended.

The researcher (CH/EM) rang each GP surgery and interviewed the administrative staff with a series of questions relating to how the discharge summaries were used in relation to medication changes using an interview guide (see appendix A). Questions specific to the paediatric population such as how the GP dealt with unlicensed medicines as an example were

incorporated as previous studies (Wong et al 2006) have highlight problems with obtaining unlicensed medications in children. The responses were recorded onto a structured data collection sheet (see appendix B).

The semi-structured interview data was quantitatively and qualitatively analysed.

The following variables within the interview schedule were analysed quantitatively in terms of content: -

- Frequency of Discharge letter receipts (Yes or No)
- The number of TTAs received by post or email
- The date the discharge letter was recorded as received to calculate the time it took post discharge.

The other data sets were analysed using framework analysis by Ritchie and Spencer (Ritchie and Spencer, 1994) with the following stages: -

- Data entry and processing double entry of interview transcription forms to ensure reliability (118 GP interviews in total of which 93 have been entered twice)
- Familiarisation of the interview data collected and identifying a thematic framework – initial framework based on the question guide (for initial framework see appendix H)
- Coding All interviews were coded and indexed using NVIVO 10.
 Two researchers CH and MW individually coded 10% of interviews and compared differences, with the framework modified and finalised (see appendix I)
- Charting Findings were charted according to the themes

- Mapping and interpretation

3.3 Results

3.3.1 Stage 1 hospital discharge

Over the 5 week prospective data collection period, 142 patients (64 female and 78 males, age range 1 month – 18 years) were discharged on 501 medication orders. On comparing the initial discharge letter and pharmacist amendments, 99/501 (20%) of medication orders were found to be discrepancies and 47/142 (33%) of patients had at least one discrepancy with a median of 1 discrepancy per patient (range 1 – 12 discrepancies per patient, interquartile range 1 – 3).

The discrepancies were clinically assessed for the potential severity of harm it would pose to the patient, if it had not been identified upon discharge. Of the 99 discrepancies, 77 were found to be of minor severity (range of mean score 0.18 - 2.98), and 22 discrepancies (15 patients) were found to be moderately severe (range of mean score 3 - 6.38). An example of a minor and moderately severe discrepancy is provided in tables 15 and 16 respectively.

Patient number	Age	Weight	Description of discrepancy	Mean score
22	14 years	28.8	Initial TTA does not state that Ranitidine 90mg BD should only be used "whilst on Ibuprofen only"	1.71

Table 15 Example of a minor severe discrepancy on a hospitaldischarge letter

Table 16 Example of a moderately severe discrepancy on a hospitaldischarge letter

Patient number	Age	Weight	Description of discrepancy	Mean score
138	3 years 5 months	13.2	Fludrocortisone 50mcg tablets to be taken every morning missed off initial discharge letter by doctor, added on by pharmacist to final letter	5.83

In summary, during the 5 week data collection between April – May 2011, 22 discrepancies with the potential to cause moderate harm was found in the 501 discharge medications ordered representing 4% of all medications ordered having 1 unintentional moderately harmful discrepancy. In terms of patients 15 out of the 142 patients seen during the study period had a discrepancy that was moderately harmful meaning that over 5 weeks the % of patients who would experience harm if the discharge letter was not amended by a pharmacist was 11%.

Timeliness of discharge letter reaching the GP

After contacting the GPs of the 142 discharged patients 72 hours post discharge; 49% had received the discharge summary and 45% had not, the remaining 6% were patients who were discharged without a GP.

3.3.2 Stage 2 GP receipt and reconciliation process

Between June and July, 118 GP surgeries were identified from the 154 patients discharged over the 5 week period. Each of the 118 GP surgeries were contacted and interviewed using the same semi structured interview schedule. Only 72 out of 118 (61%) of GP surgery receptionists or administrators were available for interview. The results are summarised quantitatively and qualitatively in the next section.

Quantitative findings

From the 72 GP surgeries contacted, 66 (92%) reported that they received the discharge of which 50 received a paper copy, 13 received an email, 3 received both email and a paper copy, and one reception staff was unsure. Only 6 GP surgeries reported that the discharge letter was not received.

From the 66 GP surgeries that reported that the discharge letter was received, two did not know the date of receipt. The time recorded for receipt of discharge letter from the GP surgeries ranged from 4 days before discharge to 27 days later with the median time being 5 days (interquartile range 2.5 - 6.5 days). For the 3 GP surgeries that had received the hospital discharge letter before the discharge date, these surgeries were further

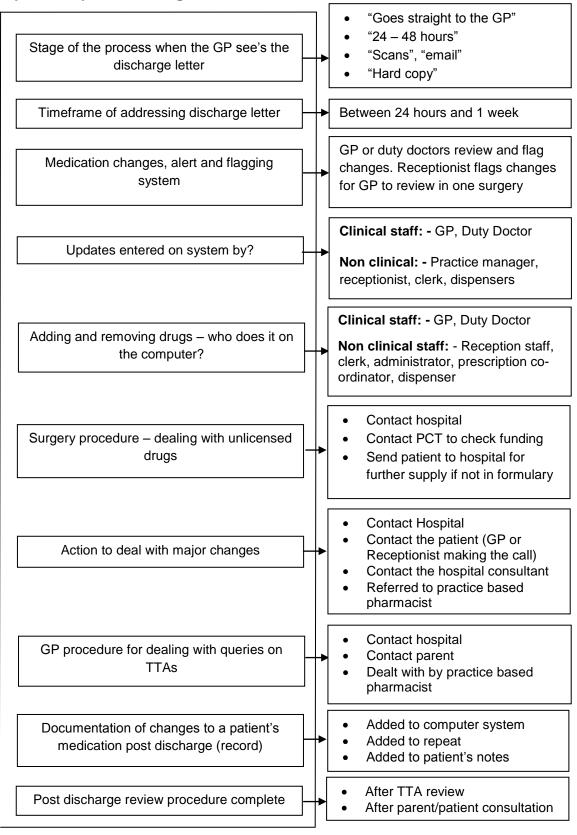
questioned and only one surgery provided that the date of admission as opposed to discharge letter date was recorded on the system. Only 25 out of 66 (38%) GP surgeries had received their patient's discharge letter within 72 hours.

Qualitative findings

From coding of the interview transcripts, the initial framework was expanded to provide a final framework of codes across ten major themes, representing each stage of the reconciliation process (see appendix H for the finalised coding framework). From the coding framework and themes, a model was constructed based on the themes and responses from the GP surgery staff responses. A summary diagram of GP's medication reconciliation process of amending the patient's medication list according to the discharge letters, and staff involvement at various stages of the process extracted from the interview responses are summarised in the process model figure (see figure

5).

Figure 6 - The main themes of the coding framework for the GP surgery post hospital discharge interview



The interviews with the GP surgery staff provided insight into how long it took before a discharge letter was addressed and seen by the doctor, the variation in the medication reconciliation procedure after hospital discharge at each GP, and also insight into how GPs dealt with queries and managed the request for prescribing an unlicensed medication for a child.

Time frame for addressing the discharge letter

From the interview of the GP surgery staff two weeks post discharge, staff provided varied responses to when a GP would review a patient's hospital discharge letter. The majority of GP staff responses were that the GP saw the discharge letter after a procedure of scanning the paper discharge letter onto the system.

"After the letter has been scanned on patient's record, doctor is notified" **Patient 281's GP**

"GP sees the letter as soon as it is scanned and in their mailbox." **Patient 203's GP**

There were also GP surgeries where the discharge letters were passed directly to the GP before they were scanned onto the patient's medication record on the electronic system.

"The discharge letter goes to the doctor's basket before scanning onto the system" **Patient 221's GP**

Variation of the GP practice medication reconciliation procedures

The GP surgery staff interviews highlighted that at most surgeries interviewed the GPs were involved in the reconciliation of the patient's medication after hospital discharge. There were occasions where staff had indicated that other support staff such as the duty doctor, receptionist, dispenser and administrative staff also contributed to various stages of the reconciliation process.

Support staff involvement in the reconciliation process

Adding or removing drugs

When posed with the question of who was responsible for adding and removing drugs on the patient's record at the GP surgery, most surgeries that were interviewed indicated that it was the GP. However, a few surgeries indicated that other support staff were also involved with some indicating that it was under the instruction of the GP or that support staff were used when the GP was busy.

"Receptionists if GP is busy" Patient 262's GP. *"Reception staff – trained"* Patient 184's GP *"Prescription co-ordinator, double checked by GP"* Patient 250's GP

Dealing with major changes

When there were major changes the patients medication on the discharge letter the GP was the main person involved in initiating the query with parents and hospitals contacted. Most GP surgeries who provided responses contacted the hospital of discharge to make an enquiry, with some responses specifying who they spoke to or requested to speak to.

"Contact the hospital - ask for the specific discharge doctor." Patient

240's GP

"Contacts the patient's consultant." Patient 299's GP

There were also GP surgeries that specified that they contacted the patient first before the hospital: -

"Contact the patient first and then hospital if problem is unresolved"

Patient 270's GP

Another approach which was given by GP reception staff interviewed were that they checked to see if the patient was going to be reviewed by the hospital consultant prior to taking any action.

"GP would contact patient for appointment unless consultant at hospital is going to follow them up" **Patient 220's GP**

Updating the system

Updates of the patient's medication following discharge were being made by practice managers, receptionists, clerks, the dispenser or prescription co-

ordinator at some surgeries with one response clarifying that receptionists were involved if the GPs were busy: -

"GP, or receptionists if GP is busy" Patient 262's GP

"Dispensers update system" Patient 263's GP

"GP sends all changes to be updated by practice manager" Patient

299's GP

"Prescription clerk or GP" Patient 246's GP

Surgery procedures in dealing with discharge letter queries and ordering unlicensed medication

When there were queries with regards to the medications reported on the discharge letter, most were dealt with by the GP. The GP either contacted the parent or hospital regarding the query.

With the GP surgery staff who reported that the GP would contact the parent first they did so either if the query was considered minor or if they wanted to see the parent in person to clarify the queries.

"If severe contact the hospital, If minor contact patient" patient 243's

GP

"Patient was contacted for follow up at the GP surgery and further clarification" patient 180's GP

On occasions where the GP surgery contacted the hospital, they contacted the hospital via the telephone number that was provided on the discharge

letter. Some GP surgeries contacted the surgery if they felt that the query and issue was described as severe by the receptionist.

"GP would call up the number on the discharge letter to enquire if there were any problems" Patient 152's GP

Some surgeries contacted the hospital after contacting the patient and establishing the problem to be complex.

"Contacts patient then hospital if more complex." Patient 233's GP

There was one GP surgery that indicated that the task of contacting the hospital regarding a query was delegated to reception staff.

"GP instructs reception staff to contact hospital" Patient 287's GP

There were variations in the policies that each GP surgery had regarding unlicensed medication. The responses from the GP surgery staff varied with some indicating that their surgery would not prescribe unlicensed medication and sent the patient back to the hospital to obtain repeat medications, some surgeries asked their PCT prior to making a decision and some prescribed the unlicensed medication as they would not deny patient their medications.

"Refer patient back to the hospital" Patient 257's GP.

"They would contact the local PCT - if this is non-formulary - they would send the patient back to the hospital to obtain supply" **Patient** 219's GP

"Hand written prescription - doctor would not deny the patient medication" **Patient 222's GP.**

3.4 Discussion

The results from this first UK prospective study on discharge letter accuracy in paediatric patients showed that a third of discharge letters written up by the hospital physicians contained discrepancies, against the patient's final drug chart. These discrepancies were identified and rectified by hospital pharmacists who were screening the discharge letters for accuracy and reconciling the medication list as part of their routine clinical work. The only similar study identified from grey literature, a retrospective review of discharge letters at a paediatric hospital in Canada indicated that 12 out of 28 (42%) of patients had at least one discharge discrepancy between the discharge medication ordered and a "best practice medication discharge plan" which was determined in retrospect, which was higher than the proportion found in this study, however a small sample was used (Ling et al 2009). A Canadian study at a general internal medicine ward for adult observed actual unintentional discrepancies between the adult discharge medication and best possible discharge medication list to in sixty-two out of one-hundred and fifty two patients 41.3% which was also a higher proportion compared with the current study (Wong et al 2008).

With regards to the possible clinical implications of medication discharge letter discrepancies, the current study showed that 22% of discrepancies at discharge had the potential to cause moderate harm if it was not resolved

190

and in comparison to the Canadian adult study which was 29.5% of discrepancies having the potential to cause possible or probable patient discomfort or clinical deterioration (Wong et al 2008). The methodology utilised by this study and the adult Canadian result differed, as a visual analogue scale with five assessors was used for this study whereas a three point scale rating by three assessors was used.

The GP surgery interviews indicated variation in terms of when the GP saw and reviewed the discharge letter. With regards to reconciling the patient's medication record following a patient's hospital discharge, a few GP surgeries indicated that reception and non-clinically trained staff were delegated tasks and contributed to updating the patient's records as part of the reconciliation process. This finding of reception and other support staff contributing to clinical tasks was similar to the findings by Swinglehurst and colleagues who identified that receptionists and administrative staff were making hidden contributions to quality and safety in prescribing (Swinglehurst et al 2011). In addition to variation in reconciliation procedures among GP surgeries, another issue that was indicated from the interview were variations in the provision of unlicensed medicines. GP surgery responses showed that there were GP surgeries that did not dispense unlicensed medications and had to check with the local PCT. This highlights a potential barrier and problem with obtaining further supplies of medication from the GP which have been found in previous studies (Wong et al 2006).

191

The clinical implications of this study have indicated that currently, the prescribing of hospital prescriptions are not accurate and require an extra step in reconciling the list via pharmacist input, with the pharmacist acting as the barrier, preventing potentially 22% of potentially harmful discrepancies from leaving the hospital. As with any form of defence, there may be weaknesses in the defence mechanism. If the study took into account the fact medication discrepancies also occur in children at hospital admission, discrepancies at discharge increases the chances of potential harm from occurrina. This study highlights that there is a need for improving the accuracy of discharge letter prescribing and further work may be required to observe how discharge letters are written up prior to a patients discharge to find reasons behind the discrepancies. There may also be a need to evaluate the accuracy of discharge letters written out of hours where pharmacist cover is reduced, to evaluate if the out of hours service is adequate to ensure that the discharge letters have been checked to ensure patient safety and reduce the risk of potential harm.

There were a number of limitations to the study. The study was conducted in one paediatric hospital in the UK and only the discharge letters that were reviewed within pharmacy operational hours were included in the study.

3.5 Conclusion

This study highlights that one in three discharge letters contained at least one medication discrepancy and required pharmacist interventions to rectify prior to completion. The presence of such a high discrepancy risk did not take into account those medication discrepancies which might not have been spotted via the pharmacist check. Interviews with staff at GP surgeries revealed that there were variations in GP surgery procedures with reconciling medication post hospital discharge. The responses suggested that nonclinical staff were involved in parts of the process in some surgeries. The complexity and involvement of non-clinical staff involvement poses a risk as not all patients were receiving a full review by the GP or clinician in the surgery. There were concerns with transmission of discharge letters from hospital to GP as less than half were received in a timely fashion. Further studies following up the parents/patients discharged from hospital, and observing GP prescribing decisions based on their interpretation of the discharge letter are required.

4.1 Background

Following on from chapter 3, it was found that discharge medication orders in discharge letters were generally accurate once seen by a hospital pharmacist who would screen the record for appropriateness, and that there were variations in the way in which medications were reconciled by the GP. The studies illustrated that the discharge letters were checked by a pharmacist prior to being sent out to the GP, and that only half were received by the GP surgery within 72 hours specified by the CQC. The study did not observe directly the impact this would have on the patient's subsequent medication regimen following discharge and whether any discrepancies or problems occurred.

4.2 Aims and objectives

The aims of this study were to observe the incidence of medication discrepancies and problems occurring in children on their continued medicines after hospital discharge, identify the root causes of the discrepancies with potential adverse clinical outcomes, and to identify existing solutions to issues identified from parents and healthcare professionals used in practice.

A three stage study was conducted with the following objectives: -

Stage 1 Identifying post discharge discrepancies, problems and its potential harm

- Determine the incidence of medication discrepancies and record problems reported by parent of children discharged on long term medications via post discharge follow ups
- Assess the potential harm that may occur as a result of unintentional discrepancies occurring at discharge
- Record and analyse the comments raised by parents in the post discharge follow up to identify common themes in relation to: -
 - problems experienced during the post hospital discharge period
 - Any interventions or actions taken by the parent or healthcare professional to resolve the post discharge problem

Stage 2 Root cause analysis of potentially harmful unintentional post discharge discrepancies

Identify the root causes of potentially harmful unintentional discrepancies

using the NPSA Root Cause Analysis toolkit

Stage 3 Healthcare professionals' perceptions and experiences of post discharge discrepancies in children post hospital discharge

- Identify problems experienced by healthcare professionals who work across the interface of care during post hospital discharge and their strategies and thoughts on reducing the problems
- To suggest solutions to an example of an unintentional discrepancy with the potential to cause moderate harm
- Summarise the findings into a modelled process map, highlighting where discrepancies and problems occur during post discharge, with suggested solutions and interventions indicated.

4.3 Method

4.3.1 Stage 1 Recruitment of parents/patients for follow-up

Rationale for the adoption of a mixed methodology/model approach to the study

A mixed methodology approach, using a range of quantitative and qualitative methods, was used to achieve the study objectives and to ensure that findings were valid, relevant to the parents and healthcare professionals involved in the management of a paediatric patient and broad in scope. Quantitative data such as the number of medications, and total number of patients followed up were used to calculate an incidence for paediatric patients with a medication discrepancy at the point of obtaining further supplies of medication from their GP. Qualitatively, a thematic analysis approach based on the methodology by

Clarke and Braun (2006) was used to draw out themes in relation to follow up comments of problems reported by parents and patients during the period between hospital discharge and follow up. Any reported actions that were taken by the parents and healthcare professionals to prevent discrepancies from occurring were also included in the analysis. By adopting this mixed method approach, the incidence of discrepancies as well as those potential problems observed by the parents that have been prevented by action from the parent and healthcare professionals were identified to ensure that the findings observations were valid.

The second stage of the study with the root cause analysis was quantitative using Root Cause Analysis tools (NPSA 2013) to aid the investigation. The final stage of the study, the focus group was qualitative as the aim was to gather multiple healthcare professional views on the problems and possible solutions in depth. A qualitative approach was adopted for this stage of the study as the results would have provided a lot more depth in terms of each professional's experiences with discrepancies and their approach to solving the problems.

In summary, by combining the mixed method approach to the study, the scope of the study covered: -

- The incidence of the discrepancies that occur in the study patient population between hospital discharge and first supply of further medication by the GP.
- Insight into the root causes of post discharge discrepancies

198

- The problems facing parents of children on long term medications after hospital discharge from the parent and patient's perspective (stage 1 comments), and also from the healthcare professional's perspective (stage 3).

A summary of the methodological approach for the MERRY-PD study is summarised in figure 6.

Figure 7 Summary of the methodological approach and expected outcomes for the MERRY-PD study

Methodological approach	Outcomes		
Stage 1 Follow up study			
Quantitative – Collecting data on follow up patient's demographics and medication details to identify discrepancies	Demographic details of the study participants Incidence of discrepancies that appear as a difference between the discharge letter medications and the post discharge follow up medication list		
Qualitative – Collecting comments from parents of follow up patients to analyse the problems and solutions reported in terms of common themes	Descriptive summaries of problems occurring between hospital discharge and post discharge that have not appeared as a discrepancy and have been prevented Parents perspective of post hospital discharge issues: - Information regarding a parents experience with post hospital discharge problems and solutions		

Stage 2 Root Cause Analysis	
Quantitative – using the NPSA Root	Provides further details of the possible
Cause Analysis tools to identify causes to	causes of discrepancies occurring post
discrepancies with a potentially moderately	discharge and areas that may need
harmful outcome	addressing

Stage 3 – Focus group		
Six participants: - consisting of GP,	Healthcare professional perspective of:	
community pharmacists, hospital	Post hospital discharge problems and	
pharmacist, hospital doctor and nurse.	possible solutions	

NHS REC ethics favourable opinion and local R&D approval was granted across all sites for all three stages of the MERRY-PD study.

Setting

Paediatric hospital wards across all available specialities across five hospital sites in England, four in London and one in Stockton-upon-Tees.

Study duration

Eight month recruitment period from March - October 2012

Stage 1 Recruitment of parents/patients for follow-up

Trained healthcare professionals (clinical pharmacists, paediatric research nurses and paediatric clinicians) from the hospital sites recruited parent/carers of children aged less than 18 years of age at ward level that were on at least one long term medicine at the point of hospital discharge.

Inclusion criteria

Patients who were eligible for the study were any children who were on long term medications at admission admitted to the paediatric wards at the study hospitals for longer than 24 hours. Patients who were discharged back to the care of the GP in the UK and whose parent had given written consent and provided contact information prior to discharge were included.

Exclusion criteria

Non-English speaking parents, Non-English patients aged 16 and above, or patients who were transferred to another hospital or discharged to care settings outside the UK were excluded from the study due to resources.

Recruitment strategy

Patients who were eligible for the study were identified by the clinicians (hospital pharmacist and doctors) and given a parent information leaflet and age-specific patient information leaflet (see appendix J for sample leaflets). The design of the patient information leaflets had been reviewed by the MCRN young person's advisory group to ensure the contents of the leaflets were age appropriate (see appendix K for the young person's advisory group feedback on the initial leaflet design). This was non-randomised and each consecutive parent and parent identified as eligible during the study period was approached depending on the availability of trained staff.

Written consent from the parent and assent from the child were obtained prior to discharge for the patients who were less than 16 years of age (see appendices L and M for sample consent and assent forms). For parents who were aged 16-18 years, consent was taken from the patient if they had taken over the management of their medications with the GP and community pharmacist. Patients were given the option of a home visit (for patients based in London) or telephone call follow-up.

Follow up procedure and data collection

After consent at ward level, the following information regarding the patient was recorded: the patient's name, address (for home visits), name of parent, contact

number for follow up purposes. The following relevant demographic and admission information were recorded: -

- Patient's age, gender
- Ward of discharge and speciality
- Date of admission and discharge
- A list of the patient's medication recorded on the discharge letter

Parent recruits were followed up by a research pharmacist (CH) 21 days after discharge by telephone. The parent was asked if they had contacted their general practitioner (GP) for further supplies of medication and if they had the research pharmacist started the interview on the telephone or arranged a convenient time for a home visit. If the parent had not been in contact with the GP for further supplies, the research pharmacist rescheduled the follow up to when the parent was expecting to have obtained further supplies at a later date. During the home visit or telephone interview, parents were asked for a list of their medications following the further supply obtained by the GP. The research pharmacist recorded the list of medications the patient was taking on the data collection form and noted any differences between what was written on the discharge letter and what the parents reported. Any discrepancies between the medications reported during the follow up interview and the discharge letter medications were questioned and followed up with the GP or community pharmacist as appropriate. Any other comments provided by the parents in

relation to any other problems related to the discharge or supply of further medication after hospital discharge were recorded.

Quantitative data analysis procedure

The demographic information collected from the parents analysed using descriptive statistics with the aid of the statistical software SPSS version 20.

The discrepancies identified between the discharge letter and post discharge medication list were classified by two pharmacists CH and ST into intentional (where there was a reason behind the post discharge discrepancy for example the GP or hospital consultant adjusted the dose), unintentional (where the GP may not have intended to change the prescription), or unclassifiable from the information collected.

The incidence of discrepancies and types of discrepancies from the paediatric patients followed up over the 8 month period was calculated using the following formula:

Incidence of paediatric patients followed up with at least one post hospital discharge discrepancy (before classification) =

Total number of patients with at least one discrepancy (any type) post hospital discharge × 100

Total number of patients followed up

The incidence of paediatric patients with at least one unintentional post hospital discharge discrepancy =

Total number of patients with at least one identified unintentional discrepancy post hospital discharge × 100

Total number of patients followed up

The 95% confidence intervals were calculated for the incidence of discrepancies.

The unintended discrepancies were clinically assessed by six clinicians (research nurse, consultant paediatrician, hospital consultant pharmacist in paediatrics, General Practitioner and two community pharmacists). Each of the clinicians was given descriptive accounts of each discrepancy with the patient's age, weight and gender provided. For each discrepancy, each judge was asked to assign a severity score on a validated visual analogue scale ranging from zero representing no harm to the patient and 10 representing death (Dean and Barber 1999). Six clinicians were used to assess the severity as opposed to the 5 suggested by Dean and Barber (1999) as the judges were invited both to severity assess the discrepancies and attend the focus group. The judges scored the severities individually and the mean score for each discrepancy was calculated and were considered minor for scores of less than 3, moderate for scores between 3 - 7 and severe for scores above 7 (Dean 1993).

Qualitative data analysis procedure

The comments made by the parents/patients via telephone and home visits were recorded directly onto a data collection form, transcribed onto an excel spreadsheet and exported into NVivo© for coding and retrieval. The research pharmacist (CH) a full time PhD student with no involvement in clinical pharmacy services at the hospital sites, who was involved in the follow up of parents and patients, conducted the analysis. An inductive qualitative thematic analysis technique (Braun and Clarke 2006) was used to identify emergent themes from the data in relation to problems experienced by the parents, and solutions or actions that the parents, patients or healthcare professionals took to address problems which may or may not be a formal intervention. The research pharmacist undertook the following stages of the thematic analysis: 1) Familiarisation – reading through the data collection forms; 2) Generating initial codes; 3) Searching for themes across the codes; 4) reviewing the themes; 5) defining and naming the themes; 6) producing the report (Braun and Clarke 2006).

4.3.2 Stage 2 Root cause analysis of potentially harmful unintentional post discharge discrepancies

A Root Cause Analysis investigation was carried out for each patient who had at least one unintended post hospital discrepancy identified as moderately harmful identified in the previous stage of the study. This was conducted in retrospect and utilised existing information collected during the follow up. The research

pharmacist involved in the post discharge follow up conducted the RCA with the aid of the National Patient Safety Agency (NPSA) toolkit (NPSA 2013). Attempts to seek additional information from the hospital, GP and community depending on the nature of the discrepancies were made where appropriate.

4.3.3 Stage 3 A focus group of healthcare professionals' perceptions and experiences of post discharge discrepancies in children post hospital discharge

A focus group was conducted to find out healthcare professionals' perceptions and experience of post discharge discrepancies. Hospital healthcare professionals working at the main study site in London, local community pharmacists and GPs were invited to participate in the focus group and sent an invitation via email. All who were invited agreed to participate in the focus group. The focus group consisted of a hospital consultant pharmacist, hospital consultant paediatrician, a research nurse, GP, and two community pharmacists (one locum and one superintendent pharmacist). The focus group session was audio recorded, lasted an hour and thirty minutes and was moderated by a research pharmacist using a question guide. The participants were also given an example of a post discharge discrepancy with the potential to result in moderate harm and were asked to discuss the possible root causes and suggest solutions. Recordings were transcribed verbatim with the details of the participants made anonymous, and was transferred to NVivo version 10 to assist with the coding and retrieval stages of data analysis. The data was

coded using an initial coding framework based on the question guide for the focus group. To ensure reliability of the coding, the first 10 minutes of the focus group was coded independently by two researchers CH and MW (both PhD students at the Department of Practice and Policy at the UCL School of Pharmacy and have received training in qualitative data analysis). The two researchers discussed the differences in coding, and modified the framework. The finalised coded responses were charted by case for each respondent, for example the GP responses to each them. The data were interpreted in relation to the objectives and guestions asked.

4.4 Results

4.4.1 Stage 1 Recruitment of parents/patients for follow-up

Quantitative findings from the 21 day post discharge follow up study

During the study period, 285 patients aged from 1 month up to 18 years (1524 medications ordered on the discharge letter) across the 5 hospital sites were recruited, of which 182 (64%) (1087 medications) were followed up. The demographics all patients who consented, followed up and details of the patients who were not followed up with the reasons are provided in tables 17 and 18, respectively.

Total number of patients consented for the	285	
study		
Gender	Female: - 131 (46%)	
	Male: - 154 (54%)	
Age range	1 week – 18 years	
Specialities responsible for the care of the	Adolescent team, Cardiology, Clinical	
patient at ward level prior to discharge	Haematology, Cystic Fibrosis,	
	Dermatology, Gastroenterology, General	
	Medicine, Neonates, Neurology,	
	Orthopaedics, Surgery, Renal,	
	Respiratory Medicine, Urology	
Number of medications on TTA	1524	
Number of medications per patient (mean	5.35	
average)		
Number of medications per patient (range,	Range: 1 – 25 medications per patient	
median, interquartile range)	Median: - 5 medications per patient	
	Inter-quartile range: - 3 – 8 medications	
	per patient	
Demographics of consented patients w	rith a complete follow up	
Total number of patients followed up	182	
Gender	Female: - 86 (47%)	
	Male: - 96 (53%)	
Age range	1 week – 18 years	
Specialities responsible for the care of the	All specialities except for Clinical	
patient at ward level prior to discharge	haematology	
Number of medications on TTA	1087	
	5.97	
Number of medications per patient (mean		
Number of medications per patient (mean average)		
	Range: 1 – 25 medications per patient	
average)	Range: 1 – 25 medications per patient Median: 5 medications per patient	
average) Number of medications per patient (range,	Range: 1 – 25 medications per patient	

Table 17 Demographics of patients followed up post hospital discharge

Table 18 Reasons why parents consented were not followed up posthospital discharge

Reasons why parents were not followed up	Number of parents
Lost to follow up (did not answer the telephone on 3 occasions	68
Child received a discharge letter without medication ordered	16
Child discharged without a discharge letter	9
Not discharged at the end of the study	3
Discharge plan was changed to local hospital transfer	3
Withdrew from the study	3
Not followed up due to social reasons	1

Sixty-seven patients out of 182 patients who were followed up had at least one post discharge discrepancies.

Hence the incidence of paediatric patients experiencing at least one discrepancy of any type over the 8 month study period was: -

67 (Patients with at least one discrepancy identified by the post discharge follow up)

x 100 = 37%

182 (Total number of patients followed up)

Of the 67 patients, 48 patients had at least one intentional discrepancy, 22 patients had at least one unintentional discrepancy, and 9 patients had at least one unclassifiable discrepancy.

Hence the incidence of paediatric patients experiencing at least one unintentional discrepancy over the 8 month study period was: -

22 (Patients with at least one unintentional discrepancy identified by the post discharge follow up) × 100 = 12%

182 (Total number of patients followed up)

A detailed breakdown of discrepancy results from the post discharge follow up are given in table 19 and examples of each type of discrepancy in table 20.

Table 19 Medication discrepancy details identified from the post hospital discharge follow-up of parents of paediatric patients

Total number of medication discrepancies (all	121
types)	
Percentage of medications ordered on the	(121÷1087) × 100 = 11%
discharge letter that are medication	
discrepancies	
Total number of patients with discrepancies (all	67
types)	
Percentage of patients with a discrepancy of	67÷182 × 100 = 36.8% (Confidence
any type	Intervals: - 95% CI = 29.8 - 43.8%)
Number of discrepancies (all types) per patient	1.8
(mean)	
- Number of unintentional discrepancies	29 unintentional discrepancies
 Number of patients with unintentional 	22 patients
discrepancies	
- Number of unintentional discrepancies	1.3 unintentional discrepancies per patient
per patient	
- Number of intentional discrepancies	77 intentional discrepancies
- Number of patients with intentional	48 patients
discrepancies	
- Number of intentional discrepancies	1.6. intentional discrepancies per patient
per patient	
- Number of unclassifiable discrepancies	15 unknown discrepancies (in relation to the
	classification of whether it is intentional or
	unintentional)
- Number of patients with unknown	9 patients
discrepancies	
- Number of unclassifiable	1.7 unknown discrepancies per patient (in
discrepancies per patient	relation to the classification of whether it is
	intentional or unintentional)
	intertional of dimiteritional)

Discrepancy classification	Example
Intentional discrepancy	At discharge the following was prescribed on the discharge letter: Phenoxymethylpenicillin 125mg BD (125/5ml - 5ml twice a day), indefinitely. Post discharge follow up 4 weeks later: - Parent told research pharmacist during home visit that the patient dislikes taking this. Hence the patient was prescribed 2.5ml twice a day (250mg/5ml) by the GP, a lower volume to try and get patient to take it.
Unintentional discrepancy	At discharge the following was written on the discharge letter: Carvedilol 3.125mg tablets, directions: - 0.6mg orally twice a day. Post discharge follow up 3 weeks later: GP supplied 5mg/5ml liquid, directions: - 0.6mg orally once a day.
Unclassifiable discrepancy	At discharge the following was written on the discharge letter: Carbamazepine tablet, 400mg orally at night to continue GP as this works well with the patient. Post discharge follow up 5 weeks later – Mother reported that the GP prescribed 100mg tablets, directions: - take two tablets twice a day, and community pharmacist dispensed Tegretol 100mg tablets, directions: - take two tablets twice a day.

Table 20 Examples of unintentional, intentional and unknown discrepancies post hospital discharge

The severity assessment of the unintentional discrepancies resulted in 14/22 patients (19 medications) with at least one potentially moderately severe discrepancy and 10 patients (10 medications) with a potentially minor discrepancy.

Hence the total incidence of patients experiencing a potentially moderately severe unintentional discrepancy was 7.7% (95% Confidence interval 1.1% - 16.0%): -

14 (patients with at least one unintended discrepancy considered moderately harmful)

x 100 = 7.7%

182 (Total number of patients followed up)

Qualitative findings from the comments made by parents and patients during the 21 day post discharge follow up

Three main themes were identified from the comments made by the parents at follow up: 1) Problems reported by parents/carers and patients, 2) descriptions of mechanism of obtaining further supplies of medication and 3) Action or interventions to prevent problems. Each of the themes was also classified into subthemes in relation to the organisations, professions and people involved.

A summary of the themes, subthemes and descriptions of the problems or mechanisms of obtaining further supplies and action is summarised on table 21.

Table 21 Thematic summaries of post hospital problems, actions to address the problems and mechanism for
obtaining further supplies of medication

1) Problem	2) Mechanism of supply	3) Action
 Hospital related Information provision at discharge Verbal non documented dose changes in hospital Supply of medication at discharge Quality of advice and counselling given at discharge Communication between different hospitals looking after the same patient 		 Hospital action Hospital supplies the special medication that the community pharmacy cannot supply Patient given sufficient supply of new medication until next review Nurses helped with arranging further supplies of medication Hospital pharmacist provides a supply letter with details of how to source the special for the community pharmacist
 GP related Prescribing a different medication formulation, reason unknown Prescribing a different medication or medication formulation from hospital due to cost or formulary reasons Refusal of prescribing and restriction in supplies from GP Refusal to prescribe unlicensed or nonformulary medicines Refusal of prescribing because of lack of clinical information for GP Prescribing long term medicines as acute or on an ad hoc basis rather than repeat Time lag in updating records based on hospital discharge and outpatient changes Discrepancy in dose 	 Electronic transmission of prescription Email of online request of repeat medication 	 GP action Changes medication according to discharge letter without parent/patient consultation GP consults the parents to go over new medications and reviews the discharge letter Receives blood results from hospital and intervenes accordingly Changes the dosage form or strength to help with adherence Advises parent to order before hospital supply runs out GP surgery policy for any label changes to be referred to GP for review and consultation with parent

1) Problem	2) Mechanism of supply	3) Action
 Community pharmacy related Availability of specials or medications not routinely used in community pharmacy Brand, strength or formulation variances from hospital supply Shelf life and pack size Labelling products as directed Delays length of time to obtain medications 	 Prescription collection service Community pharmacy home delivery 	-
 Parent related Parents capacity to interpret discharge letters Parent not going to the GP for review Parents competing roles and time 	Conventional paper order of repeat	 Parent action Parents acting as liaison between GP and hospital Decision maker on who to contact when the patient is unwell Keeping correspondences in a file Planning ahead and ordering medication in advance Parents informing GP of changes Parents dropping off discharge letters at GP reception Staying with the same GP and community pharmacist Changing community pharmacists Borrows medication from friends when short Overrides the labelled instructions from the community supplied medication as the instructions are not up to date

Theme 1 Post discharge problems reported from parents/carers or patients

Post discharge problems identified were related to organisations such as i) the hospital, ii) the GP and iii) the community pharmacy, or the individual parent.

i) Hospital related post discharge problems

There were five themes of problems identified that were related to the hospital setting:

A. Information provision at discharge

Patients who were discharged without any of their regular medications on the discharge letter experienced problems with obtaining further supplies from their GP. This was discovered at the point of request for further supplies when it was found that the GP would not prescribe it without evidence.

The GP would not prescribe Adcal to the patient because it was not listed on the discharge letter. The parent had to bring a box of medication dispensed by the hospital before the doctor agreed to prescribe the medication (Patient L204).

Mother had a problem with obtaining an ACCU-CHEK® device for the patient as it was not on the hospital discharge letter *(Patient L050)*.

The two examples illustrated that the presence of information on the discharge letter was important evidence required for the continuation of the medication post discharge via the GP.

B. The oral non-documented dose changes in hospital

Dose changes that were made by the hospital physicians via consultations with parents, which may not have been documented or communicated to the GP or community pharmacist, were found to result in inconsistent labelling information. These became problems for the patients when they were attending school or a hospice as these care settings were unwilling to deviate from what was instructed.

Carer had been instructed orally by the consultant to wean the patient off clonidine. The carer had nothing in writing to support this suggested tapering of dose. The school will not deviate from the labelled instructions on the patient's medication labelled by the community pharmacy which corresponds to the GP's record (*patient L153*).

Patient was prescribed carbamazepine 100mg tablets with the GP directing the patient to take 200mg twice a day, but the discharging hospital directions were – take 400mg at night. Mother explained that the consultant suggested tapering the patient's dose or varying it to see if it worked. Nothing in writing and GP not informed. The consultation had taken place orally (*patient L172*).

Mother gave feedback saying paracetamol "use as directed by the bottle," is not acceptable at the children's hospice. Same issue with ibuprofen. The hospice was happy if it was labelled with a dose and directed as required *(patient L021)*.

C. The supply of medication at discharge

The supply of medications from the hospital at discharge in some cases was insufficient. It did not provide the parents and carers with sufficient time to arrange for more from the GP.

Hydrocortisone colifoam 125mg. This was provided to the patient on the ward during admission and not a POD (Patients Own Drug as endorsed on the patient copy of the letter the parent of the patient told the research pharmacist at follow up). When the patient was discharged this medication ran out 5 days later (*Patient L100*). Mother stated that the diclofenac 5 day supply was low. Mother had to go to the GP for further supplies which was given as paracetamol

and codeine (*Patient L165*).

D. The quality of advice and counselling given at discharge

There were issues and concerns raised regarding the advice and counselling provided by hospitals at discharge. The advice that were missing were related to whether or not the patient required continuation of the medication, information on interactions, and also advice on how patients should have been weaned down on analgesic use. There were also problems relating to a lack of hand over of care from hospital staff to

the patient or carer, for example reminders or prompts of what time the patient's dose of medication was last given.

Mother said she was going to see GP see the GP at 1pm later on in the day (during the follow up phone call). She said she did not know what was going on and for how long her child was meant to be on penicillin V for, what it was for, and what diagnosis (*patient L074*).

Mother was concerned about drug interactions between ibuprofen and methotrexate and felt she could have had more advice on it from pharmacy. Nurse did not point out the end dates of analgesic......(patient L009).

E. Communication between different hospitals looking after the same patient

In the cases where a patient was cared for and managed between two different hospitals, problems relating to the conflicting advice and doses were identified from the follow up. This suggested a lack of communication between the two settings.

Patient was shared care between two hospitals. Confusing as one hospital would try to stop and review whereas the other would end up picking up the pieces (*patient L047*).

ii) GP related post discharge problems

Problems that related to the GP in terms of prescribing or refusal of prescribing were identified from the follow up comments. Also GPs were found to be prescribing long term medications on an acute basis, updated the patient's dose following a lag period or restricted the supply quantity of medication, all of which created problems for the patient.

A. Prescribing a different medication formulation without a known reason

It was identified that at follow up, some GPs decided to switch their patient's medication over from one formulation to another.

Sodium Valproate and Levetiracetam were dispensed as tablets from the GP, where the hospital had dispensed liquid. The parent did not provide further details regarding the decision from the GP (patient L049).

B. Prescribing a different medication or medication formulation from hospital due to cost or formulary reasons

Information on the reasons why the GP would not prescribe the formulation dispensed by the hospital were discussed in a few follow ups. The reasons that were given by the GP were cost and also PCT suggestions of cheaper alternatives.

Mother said Patient was discharged on warfarin liquid on discharge. GP would only prescribe tablet. Mother wanted the patient to be kept on warfarin liquid as she wanted consistency. Mother thought that the

reason behind this decision was cost as she had spoken to the chemist, and the chemist claimed that there were no problems with obtaining the product. The patient (10 years of age) was finding it difficult to swallow tablets (**patient L116**).

Patient would be kept on the same brand under normal circumstances, however if the PCT suggests they use a cheaper alternative, they will go for the cheaper one (patient L062).

C. Refusal of prescribing and restriction of supplies from the GP

GP prescribing of products that were either nutritional supplements or feeds were reported as restrictive and in some cases the GPs were refusing to supply the product upon request.

Parent reported that the GP was reluctant to prescribe ensure for the patient. The patient has lost a lot of weight (patient L183).

Parent reported that neither the GP nor hospital would prescribe the VSL probiotic (patient L208).

D. Refusal to prescribe unlicensed medication

Patients prescribed unlicensed medications at discharge were found to experience problems with continuation of supply from the GP. Some GP surgeries were refusing to prescribe unlicensed medication and reasons given were that it was not in the formulary or the PCT would not permit the

prescribing. The refusal of prescribing of unlicensed medicines were problematic in cases where the patient did not live close to a hospital.

Glycopyrollate - GP refused to supply 2mg tablets. This was prescribed on 21/8/2012 whilst the patient was an inpatient. Patient is currently obtaining this from hospital (patient L079).

When the parent went to the GP for further supplies of diclofenac oral liquid, they were told that it was not in the GP's formulary. Doctor said that if it was licensed, they could prescribe it, but if not they could not prescribe it as the PCT would not permit this **(patient L165)**.

The discharge letter did not specify brands of medications that were unlicensed but had the parents were given a note to present to the GP and community pharmacist after discharge. GP fax sent to discharging hospital - (dated 26/6/2012) informing the hospital that the they were unable to prescribe 1. Melatonin, 2. Clonidine, 3. Paraldehyde 50/50 with olive oil enema or glycopyrollate as they were all unlicensed. Mother explained that the GP did not want to prescribe medicines that were unlicensed. Mother said the GP eventually prescribed it, as she insisted that alternatives were inconvenient for the parent. The alternatives were the hospital of discharge further away from where the patient lives or a local hospital 20 minutes away (patient L154).

E. Refusal of prescribing because of lack of clinical information from the GP

One of the reasons behind GP refusal of prescribing of a medication was a result of a lack of clinical information that the GP had access to, for example blood results that were being taken in a hospital setting.

Mother obtains azathioprine from hospital as GP reluctant to prescribe as no blood test results (patient L219).

F. Prescribing long term medications as acute or on an ad hoc basis rather than a repeat

There were situations where the long term medications were prescribed as an acute medication and not put on the GP repeat. Parents who experienced this expressed that they were aware that the medication was intended long term but required them to request the medication every time they required it.

Mother had to consult the doctor (GP) every time the patient required a further supply of long term medications. Not on repeat (patient L238).

Patient consulted the GP regarding 2 weekly blood tests, as patient's condition arthritis has not become stabilised. Mother obtained a repeat of the methotrexate. An appointment to see the GP was required every time before GP would write the prescription. Further supplies were made by after a consultation with the GP and not via a repeat slip request. The patient also had monthly reviews with the

consultant rheumatology doctor in hospital where the patient's condition and treatment was monitored (patient L212).

G. Time lag in updating records based on hospital discharge and outpatient changes

There were some patients who had medications dispensed by the community pharmacist which had labelled instructions that were different to the hospital recommended instructions. Parents believed that the reason behind this discrepancy was as a result of a time lag in updating records at the GP surgery. As a result some parents were overriding the instructions on the label.

Mother states that omeprazole dose changed from 10mg/5ml - 5ml to 6ml OD. Domperidone from 1.5mg to 2mg QDS. Local hospital had changed the dose based on changes to the patient's weight in early May 2012 during the hospital ward admission, however GP had only just updated this a week prior to follow up (around 11th June 2012) (patient L033).

Mother had been overriding instructions on the label. GP was not up to date with changes done in hospital and may not have read the letter. Patient was still on the first discharge letter dose (patient L046).

H. Discrepancies in doses between hospital and GP

There were cases from the follow up where parents had expressed that there were discrepancies between the hospital and GP dose and at times they were not sure why. One mother who was a clinician suggested that the GP doesn't calculate the dose, even when the mother took the lead (patient L228).

Community pharmacy related post discharge problems

Many of the post hospital discharge medication problems expressed by the parents regarding the community pharmacy were issues related to the availability of specials, variations in formulations and medication that were not routinely used in community pharmacy. There were five key issues that were highlighted from the comments made by parents with examples of each given.

A. Availability of specials or medications not routinely used in community pharmacy

The follow up comment revealed that one of the reasons why parents were having to obtain further supplies from the hospital was not necessarily because the GP refused to prescribe the medication. There were cases where the community pharmacy could not find the supplier to source the medication.

The community pharmacist could not find a supplier to source sodium chloride oral solution (patient L010).

Dalteparin. Parents tried many community pharmacies, many didn't stock it. So patient had to go to hospital of discharge who kept it (Central London). Their local hospital in Kent did not have it. Research pharmacist enquired if the dalteparin had stopped - dad said hospital said to continue for 6 weeks. Patient going to have ultrasound to see if the clot has cleared then review its medication then (patient L102).

B. Brand, strength or formulation variances from hospital supply

There were situations raised by parents that patients were provided with different brands of special medication which also required different storage conditions. This ranged from vitamin D formulations, sugar free paracetamol for the patient on a ketogenic diet to sodium valproate and captopril.

Mother said chemist brand of captopril needed refrigeration, but the hospital supply could be stored at room temperature. The chemist ignored the mother's discharge letter which gave information on how to get Kid Cap from the suppliers the hospital got it from as the chemist got it from their local supplier and could not use the hospital supplier (Patient L122).

C. Shelf life and pack size

Concerns were raised by parents regarding the self life and pack size of the medications they were obtaining from the community pharmacy. There were some occasions where patients were provided with a product that had a shorter shelf life or a different pack size which was not convenient as it meant that the patient ran out of supplies more frequently

Lisinopril - short shelf life in GP primary care, long shelf life with hospital (patient L124).

Omeprazole 5mg/5ml - 20ml OD. 70ml bottle, hence one bottle lasts 72 hours. The issue was raised with the GP, but GP still prescribed 5mg/5ml (patient L170).

D. Labelling products as directed

There were certain situations reported by parent where it was found that community pharmacists had been labelling the medications with the directions "as directed" which would have been how the prescription was written by the GP. During a home visit by the research pharmacist one patient disclosed that the patient was taking eye drops initiated by a hospital eye clinic and had to obtain further supplies from the GP. The eye drops were labelled as directed and the mother was unsure of the dose. Eventually the parent found the original letter from the eye clinic with direction instructions written in short hand e.g. OD rather than written out as once a day.

E. Delays and length of time to obtain medications

There were many occasions where parents provided some indication of how

long it took for them to obtain the further supplies of medication and for a

certain medication to come in. Examples are summarised in table 22.

Patient number	Description provided by parent/patient during the follow up
L246	Also the community pharmacist says they may not get the
	colecalciferol in time (no indication of time was provided)
L252	Patient had no post discharge discrepancies. However Dornase Alfa
	takes long to obtain from community pharmacy. This time has taken 1
	and a half weeks
L021	Problem - 24 hours to get omeprazole suspension. After discharge
	(around May). Parent had to use MUPS instead
L030	Still awaiting the sodium chloride oral solution (mum ordered this since
	the patient was discharged). Mother usually made allowances as the
	length of time varied.
L062	Takes 3 days normally supplier problem (community pharmacist) -
	took an extra 1-2 days. Community pharmacist ordered from another
	supplier. Called community pharmacy 12:06. IPO specials - 2 month
	shelf life. Community pharmacist explained that there was a problem
	with the supplier.
L089	Sodium phosphate oral solution? (described as phosphate by parent) -
	a delay occurred between GP and the chemist. 1 week delay.
L216:	Mother had no issues with the GP however community pharmacist
	would not be able to order in for 6 days in terms of getting hold of
	phenoxybenzamine as it was a special. Mother had to find another
	community pharmacy that was able to order it in for the next day.

Table 22 Parent's report of the time taken for the medication to be ordered into the community pharmacy

• Parent/Carer or patient related post discharge problems

During the course of the analysis, it was found that parents also had the potential to contribute to problems that occurred post hospital discharge in terms of the interpretation of medication information and also obtaining the further supplies. The issues that were found were: -

A. Parental capacity to interpret discharge letter

There were cases where parents reported how they interpreted the information on the discharge letter to check if the information were correct, which was concerning as parents were not clinically trained. There was one particular case which was a cause for concern and suggested that some parents may not have the capacity to interpret the discharge letter correctly.

Mother reported that she had identified issues with the discharge letter. The mother believed that the dose of ranitidine was transposed from 105mg BD where it was meant to be 150mg. Checking with the hospital, the patient was on a ketogenic diet and the ranitidine liquid was not suitable for patients on a ketogenic diet. The hospital pharmacist said, the dose was calculated and was weight based and rounded up for a ranitidine 150mg tablet to be crushed and dissolved in water and take a proportion which corresponds to 105mg (patient L142).

B. Parent not going to the GP for review

Some parents did not go to the GP for review and were only going to the GP for further supplies of medication and go with the dose prescribed and recommended by the hospital.

..... The research pharmacist contacted the parents on a second occasion and the father said that the changes were made in hospital

and he was aware that the GP record was not up to date. The parent also said that he would not go with the GP's instructions but with the hospital instructions and that he would only go to the GP for further supplies (patient L135).

C. Parents competing roles and time

There were cases where a patient may have experienced a gap in supply as a result of parents being busy with roles outside managing their children's medication.

Mother has not been to see the GP. Mother stated that for all the regular medications the patient had before, the patient usually received repeats from the GP on a 3 monthly basis. Mother said the patient had run out of montelukast, the mother did not have the time to order this for the patient as she was busy with work (Patient L076).

Theme 2 Mechanism of obtaining further supplies of medication

There were five reported mechanisms at which further supplies for children were being process and obtained:

- 1) Prescription collection service
- 2) Electronic transmission of prescription
- 3) Email or online request of repeat medication to GP surgery
- 4) Community pharmacy home delivery

5) Conventional paper order of receipt

The five mechanisms reported indicated that there were systems in place which were set up to bypass the need to consult a GP for further supplies of medication. These patients were obtaining medication via email communication, paper request slips or collecting and receiving them from the community pharmacist directly. The presence of these mechanisms of obtaining further supplies of medication did not help with reducing problems and may have potentially caused a delay of discovering a problem relating to the GP prescribing.

A problem that was discovered when the patient went to pick up the prescription. The GP record was not updated and the parent was not particularly happy because she had handed in the discharge letter to the GP reception staff by hand **(patient L071)**.

During the follow up, the parent told the research pharmacist that the community pharmacist would normally deliver the medications to the patient's home. A telephone follow up was rescheduled and when the research pharmacist was told that the community pharmacy had not delivered the medication and the mother will go to visit the community pharmacy to find out why **(patient L247)**.

In summary, the follow up comments from parents have shown examples where a system such as the prescription collection service may have delayed the discovery of post discharge problem. This may possibly have been why

some GPs were not prescribing long term medications on a repeat basis but on an acute ad-hoc basis.

Theme 3 Action or intervention to address and resolve problems related to further medication supply post hospital discharge

Actions that were taken to address and resolve problems that related to further medication supply were discussed and highlighted by the follow up data. In similarity to the problems, this theme was split into subthemes in relation to i) parent, ii) GP and iii) hospital related interventions. Interventions relating to community pharmacies were not discussed by the parents who were followed up.

i) Parent action and intervention to address and resolve problems post hospital discharge supply

From the follow up, seven ways in which the parent would try to resolve the problem were identified.

A) Acting as a liaison between the GP and hospital

The follow up comments highlighted that in some cases parents were acting as a liaison between GP and hospital as a result of a parent perceived lack of communication between the two parties.

Mother spoke to GP over the phone to communicate doses - no issues with the GP or the local pharmacy. Mother felt that it was not an efficient system to rely on the parent relaying the medication information and changes across from hospital to GP to community

pharmacy. Mother thinks that there were many links in the system where things may go wrong. It took two days for the GP to issue a repeat. Mother only had only seven days to obtain further supplies. Mother suggested it would be better if the hospital, GP and community pharmacy would communicate better for example via email (patient T267).

B) Decide on who is best to contact when the child is unwell

When a child's medical condition changed while at home, the parents had to make a decision on whom to make contact with to resolve the issue. This was based on the parents views of which healthcare professional was likely to be able to provide help based on their competence.

Patient well known by consultants, so sometimes when patient is downhill parent would contact the consultant so that mum is lead rather than the parent leading GP on what to do because sometimes it may be a specialised case (patient L047).

This could possibly explain why there are times when the changes made to a patient's therapy after a consultation with a hospital consultant may lead to discrepancies or changes in dose compared with the GP records.

C) Keeping correspondence in a file

There were a few examples from the data which showed that parents were keeping a file of records of their child's consultation with healthcare professionals across the care interfaces.

Mother kept a file of all the clinic letters that the child has, so that the next healthcare professional was able to see what has happened to the patient in between care providers (patient L038).

D) Planning ahead of ordering medication in advance

Some parents expressed during the post discharge follow up that they were aware that ordering medication and sourcing them from a community pharmacist may result in a time delay. These parents made allowances by forward planning and ordering medication many days before the medication were due to run out.

Father ordered the modified release pyridostigmine in advance as doctors (GP) had to handwrite the prescription as it was not coming up on their computer. It took a couple of days for community pharmacy to order in. No delay or omitted dose (patient L156).

E) Keeping the GP informed of changes directly via consultation or by dropping a letter off at reception

Parents were found to be acting as a liaison between the hospital and GP surgery. The follow up comments made suggested that GPs were being kept up to date by the patient's hospital stay and parents would either drop off the discharge letter at the surgery or inform them of any changes. A summary of examples is given in table 23.

Table 23 Description and examples of parents' comments on informingthe GP of hospital changes

Patient number	Description provided by parent/patient during the follow up
L100	Parents informing GP of changes
	I delivered my letter to the GP by hand on the 16th, together with my
	copy of the Discharge Letter and obtained a new supply of Colifoam
	immediately, together with 280 Prednisolone 5mg and 480 Asacol
	400mg that would be needed in the near future. At this time, i.e. the
	16th of October, the GP had received no copy of the Discharge Letter
	and had to rely on my copy, and my presence, to verify our needs.
L246	Parents dropping off discharge letters at GP reception
	Mum handed in TTA to GP receptionist and the GP would call the
	parent to confirm what needs to be prescribed.

F) Staying with the same GP and community pharmacist

There were a few parents who said that they would stay with the same community pharmacist and GP for continuity.

Mother mentions that her child has stayed with the same community pharmacist as her previous home address and not the community pharmacist next to the new GP (patient L252).

Mother also mentions that she had recently moved home and may change GP but prefers the old GP and hopes she could stay with the current one (patient L246).

G) Changing community pharmacists to trying and locate the one that will stock and dispense a special medication.

In the last section, some parents stated that they would stay with the same community pharmacy, however there was one parent who disclosed that

they recently changed community pharmacy as the regular pharmacist had left their previous pharmacy.

Parents have changed community pharmacy from a chain community store to a local independent. Problems began to occur at the previous community pharmacy when the regular pharmacist left their job. Repeats were duplicated. Problems with the doses of medication as in the past a captopril liquid was ordered in which resulted in a five-fold under-dose (patient L129).

Some parents who did not take the above actions sometimes resorted to actions which may not help resolve the problem such as overriding the labels on dispensed products from the local community pharmacist with the GP prescribed directions which are not up to date. There was one occasion where a parent stated that they borrowed medication from friends as an interim measure to see them through a delay in supply.

1 week prior to the patient's admission into hospital, the tacrolimus ran out, and mum had to borrow from friends (patient L005).

Mum had been overriding instructions on the labels. GP was not up to date with changes to medications made in hospital (patient L046).

ii) GP action and intervention to address and resolve problems post hospital discharge supply

A) Changes medication according to discharge letter without parent/patient consultation

Some parents reported that they had not had problems with discrepancies and that the GP had automatically updated the records according to the discharge letter.

B) GP consults the parents to go over new medications and reviews the discharge letter

There were occasions where the GP would consult the parents to review the parent and go over to change. There was insufficient further detail to suggest if these patients were more complete or if it is a result of a normal procedure of review for the GP

C) Receives blood results from hospital and intervenes accordingly

There was one occasion where the parent said the GP was very efficient with responding to blood results from the hospital. The parent revealed that the GP surgery called the parent to tell them that the patient was low on vitamin D and a prescription was waiting for the parent to pick up (**patient L251**).

D) Changes the dosage form or strength to help with adherence

There were cases and situations where the GP made a valid intervention by changing the dosage form that was initially prescribed by the hospital to help

the patient take the medication. An example of this was a case where a patient did not like the taste of the medication and the GP had to come up with a solution of prescribing capsules and counselling the parents on putting the medication into the food to disguise the taste.

Gabapentin was changed over after GP consultation. Patient had issues with taking the gabapentin due to the taste. Gabapentin was taken for dystonias - patient recently had deep brain stimulation. Patient could not tolerate the taste of the liquid; hence the GP doctor suggested using the capsules and putting it into food to disguise (patient L141).

E) Advises parent to order before hospital supply runs out

Follow up comments revealed that some GP surgeries were advising parents to order medications in advance before the hospital supplies ran out. This may suggest that the GP was aware that it may take longer for parents to obtain certain medications from the community or just to avoid situations where parents request medications in emergency situations where they have no medication remaining.

F) GP surgery policy for any label changes to be referred to GP for review and consultation with parent

There was one example from the follow up data which highlighted that a policy in place in one particular GP surgery which prevented reception and any other non-clinical staff from changing the directions on the label of a

medication prescribed for the patient. Hence, they did not just take the parent's word for it but put a procedure in place to ensure that any changes were made during a GP consultation with the parents.

Mother has just been to see the GP in person, not the receptionist, as the reception staff says that any changes on the 'label' needs to be done by the doctor (patient L123).

iii) Hospital action and intervention to address and resolve problems post hospital discharge supply

The follow up comments made by parents expressed other than the problems experienced that were caused by the hospital, there were situations where hospitals were taking action and making interventions to resolve problems post discharge. Hospitals either made an intervention by providing extra supplies of medication that community may not have been able to supply for example acetylcysteine nebuliser, dalteparin injection and sodium chloride oral solution. In terms of the supply of oral corticosteroids for gastrointestinal or respiratory patients, some patients were given sufficient supply until their hospital review which was more than 2 weeks post hospital discharge. There were also cases where nurses or pharmacists would provide help with arranging further supplies as per two examples below: -

Mother was a bit confused about how to order (Carnitine oral liquid), and rang the metabolic nurse specialist who guided mum through the

process and went to the patient's school to have a chat with staff to explain the patient's condition (newly diagnosed) (patient L104).

Father told the research pharmacist that the hospital pharmacist had given the father a letter to take to the chemist to ensure the patient got the same brand of vitamin D (patient L248).

4.4.2 Stage 2 Root cause analysis of potentially harmful unintentional post discharge discrepancies

The possible root causes of moderate unintentional post hospital discharge discrepancies affecting the 14 patients were investigated using the NPSA tools and a summary of the possible root causes are summarised on table 24. A common theme emerging from observing the root causes in the 14 patients who had moderate discrepancies was communication between care settings.

The causes of unintentional discrepancies identified by the Root Cause Analysis were either a result of a breakdown in communication and handover from the hospital, missing information from consultations and changes, a lack of counselling or reinforcement of information from the hospital staff or the information provided on the discharge letter. With regards to the information on the discharge letter, a GP who was contacted during the Root Cause Analysis explained that the reason why the patient's domperidone was not increased in dose was because on the discharge letter, although there was a dose change in the medication details, in the drug status box, which the doctor would usually refer to before deciding if a review is required, was filled

out as "as previously" as opposed to change. Further details of the causes are summarised on table 24.

Table 24 Summary of possible root causes of unintentional discrepancies

Patient number and discrepancy description	Root Causes
Patient L020	Possible causes
At discharge the following was written on the discharge letter: - Co- Amoxiclav Duo 2.5ml PO BD. Complete 28 day course, continue until Dr's appointment. Post discharge follow up (3 weeks later): Augmentin Duo - should have been sorted before discharge (not available in hospital). Mum believed that there was some arrangement to get a supply of Augmentin duo by the hospital contacting the GP to contact the community pharmacist so it would be ready for the patient during discharge. However the GP did not receive information to prescribe this from the hospital hence there was a 24 hour gap.	 Hospital Resources: - Augmentin Duo was not available in dispensary stock throughout the hospital trust Communication factors: - Did any of the staff prompt the parent to arrange the Augmentin Duo supply with the GP.
 Patient L021 Description of discrepancy: - At discharge the following was written on the discharge letter: - Omeprazole 10mg/5ml liquid, 15mg via PEG ON, to continue with GP Post discharge follow up 6 weeks later: - It took more than 24 hours to get the omeprazole. The suspension was a purple colour from the pharmacy. May not have been kept in the fridge at some point of transporting of the medication. Parent had to use MUPs instead. 	Stability of product/Storage: - Possible incorrect storage transport conditions from supplier to community pharmacy to the parent's home.

Patient number and discrepancy description	Root Causes
Patient L025	GP factors: -
 At discharge the following was written on the discharge letter: - 1) Domperidone suspension 2.7mg NG QDS continue from GP. 2) Azithromycin suspension 70mg NG Three times a week on alternate weeks, complete 28 day course - start when co-amoxiclav course is finished. Post discharge follow up (4 weeks later): Mum reckons that the dose from the hospital was low and reported it as 0.8ml which would be 35mg. GP record stated: 35mg Monday, Thursday and Saturday. 	GP surgeries are quite busy. Would make changes if highlighted in the drug status box of the discharge letter. (Information provided by GP during the investigation). GP who writes up the prescription not necessarily the doctor who made the decision of doses due to work shift patterns.
(Last issue = 21/5/2012)	Possible hospital factors: -
 Post discharge follow up (4 weeks later): 1) Mum mentioned that GP dose of Domperidone was 1.9mg QDS and said it was the wrong dose. 2) Mum reckons that the Azithromycin dose from the hospital was low and 	The doctor responsible for writing the discharge letter may not have been the doctor who came up with the decision to change the patient's domperidone dose.
reported it as 0.8ml which would be 35mg. GP record stated: 35mg Monday, Thursday and Saturday. (Last issue = 21/5/2012)	Also the dose may have been changed by another care provider prior to admission if the patient had been in and out of another hospital.
Patient L121	Hospital
Description of discrepancy: - At discharge the following was written on the discharge letter: Amiodarone 40mg BD indefinitely.	Not enough detail on discharge letter with regards to what formulation or concentration of amiodarone liquid the patient was on.
Post discharge follow up 3 weeks later - The dosage and form are not right. Tablet form was prescribed initially but has been subsequently changed.	Possible causes GP prescribed a different concentration of amiodarone to the hospital as there was no information of what concentration of amiodarone the patient
	was using.

Patient number and discrepancy description	Root Causes
Patient L046	Possible causes
 At discharge the following was written on the discharge letter: - 1) Spironolactone oral suspension 5mg PO BD continue with GP. 2) Furosemide oral liquid 5mg PO BD continue with GP 	The dose changes were communicated between the GP and hospital via a discharge letter which may not have been received by the GP surgery.
Post discharge follow up (3 weeks later):	
 Mum says that at every hospital admission, the PODs would be relabelled by pharmacy, however, when back to the old GP, the medication is labelled according to the previous dose. Basically, tapering dose information has not been updated. Previous GP, doses did not increase as per hospital changes. Mum has been overriding instructions on the labels. GP not up to date with changes done in hospital. GP may not have read the letter. Birth - 1st discharge letter dose. New GP has gone with the doses mum provides as there are a lot of different notes to trail through due to complex patient. Mum says obtaining oral syringes under 1ml is difficult as it's not available in community pharmacy, so mum has to go to a hospital for further supplies. GP record: - Spironolactone 0.24mls (2.4mg) OD Furosemide 0.24mls (2.4mg) OD 	

Patient number and discrepancy description	Root Causes
Patient L071	Possible route causes: -
At discharge the following was written on the discharge letter: Novorapid aspart 10ml vials, 0 – 1000 units SC continuous insulin pump infusion. Continue from hospital. Post discharge follow up 3 weeks later – The 6 insulin aspart 10ml vials were supplied as directed and issued as acute. Medication issued on the date of post discharge follow up : - Mum says that the medication repeat list had not been updated from the last time prior to her daughter's stay. Mum was unhappy as she handed the letter into the GP surgery in person. Patient has gone back to get this changed. Mum has been on the phone with the doctor to enquire and ask for her child's prescription to be updated.	No communication between hospital and community pharmacy other than the discharge letter. The discharge letter may not have been received or may have been received but not reviewed during the post discharge follow up (3 weeks post hospital discharge).
Patient L124	Possible route causes: -
At discharge the following was written on the discharge letter: Carvedilol 1.6mg PO BD unspecified duration.	The hospital reviewing the patient's dose as a day case did not inform the GP of the changes via post or other forms of communication.
Post discharge follow up 8 weeks later: - Mum mentioned the doctor called to clarify dose as the GP did not receive the discharge letter. Mum mentioned that the patient was admitted on 17/8/2012 to hospital as a day case. This is where the carvedilol was increased from 1.6mg BD to 6mg BD. This TTA was not sent to the GP. GP took the parent's word for it. The most recent discharge letter the GP received was from 13/7/2012 (this was the copy that the research pharmacist used as a baseline for the follow up. The research pharmacist was not aware of a TTA for 17/8/2012 – which was 4 weeks post discharge.)	

Patient number and discrepancy description	Root Causes
Patient L111	Possible route causes
 At discharge the following was written on the discharge letter: 1) Carvedilol 3.125mg tablets 0.6mg PO BD. 2) Furosemide 50mg/5ml 5.5mg OD. Post discharge follow up 3 weeks later: GP supplied Carvedilol 5mg/5ml liquid - dose being 0.6mg OD. GP supplied Furosemide 5mg/5ml 5.5mg PO TDS 6 weeks. Mum mentioned that the post discharge further supply from the GP had a change in the strength of the dose. Mum mentioned that a GP that was not the usual GP that looked after the patient changed the strength of the medications: - furosemide and spironolactone without the knowledge of the parent. Mother contacted the surgery to have the medications rectified. GP fax showed that Furosemide 5mg/5ml was prescribed with the dose being 5.5mg OD as directed by hospital. 	 GP who wrote the prescription was not the patients regular doctor The GP may not have been familiar with prescribing unlicensed special medication. The GP did not communicate the change in concentration of furosemide to the patient.
Patient L115	Possible root causes
At discharge the following was written on the discharge letter: Chlorthiazide 25mg PO BD, POD. Post discharge follow up 3 weeks later - Mum mentioned that the GP queried the dose of chlorthiazide because the two different hospital TTAs (patient was transferred from another hospital into hospital of consent before going home) and conflicting doses. Mum was unsure of the dose exactly. Mum mentioned that the GP administrator rang the parent to confirm the dose, however mum said she was unsure. On the patient's first hospital admission - the hospital tried to put the dose of the diuretics up, but it caused the potassium levels to go up.	Lack of communication and agreement of prescribing between two hospital clinicians. GP lack of access to patient's hospital full clinical record and blood results.

Patient number and discrepancy description	Root Causes
Patient L135	Possible root causes
 At discharge the following was written on the discharge letter: 1. Omeprazole 10mg/5ml liquid. 40mg PEG OM, Continue with GP. 2. Trihexylphenidyl 5mg/5ml liquid. 6mg PO TDS 8am, 2pm, 8pm. POD/TTA. Post discharge follow up 3 weeks: - 1. GP record Omeprazole 20mg PEG OM. 2. GP record Trihexylphenidyl 3mg PO TDS Dad mentioned that he was aware that the GP was not up to date and would just follow the hospital recommended dose 	 Parent – parent only contacted GP surgery for further supplies and was aware that the dose was not up to date and would go with what the hospital consultant recommended and override GPs dosage and instructions. Communication factors: Parent was not communicating or attending reviews at the GP surgery possibly due to medicines management team investigating and reviewing the patient's medication cost.
Patient L142	Possible root causes
 At discharge the following was written on the discharge letter: 1) Paracetamol 120mg in 5ml 240mg PO QDS PRN, 5 days and review – Orbis brand. No orbis brand in stock – tablets provided instead. 2) Ranitidine tablets. 105mg PO BD. Continue from GP. Post discharge follow up 3 weeks later 1) Mum mentioned issues with obtaining the paracetamol brand (as patient 	 Parent factor: - Parents did not feel that hospital was correct in prescribing ranitidine 105mg and asked GP surgery to make changes GP
was on the ketogenic diet). Patient is currently taking paracetamol tablets. Contacted GP via telephone - issue with paracetamol orbis brand - not on GP prescriber electronic system. Community pharmacy received the outpatient letter, but has not received FP10 from the doctor yet - not a problem to source. Paracetamol – the GP doctor did not know how to write up on the script because the computer system states SF already. The clinical pharmacist at hospital was consulted and it	GP did not check rationale for the ranitidine 105mg dose with hospital.

Patient number and discrepancy description	Root Causes
 Patient number and discrepancy description was suggested that the doctor types in (as manufactured by orbis). (Orbis isn't really a brand that would come up on the system - however this brand is the most suitable for the ketogenic diet. 2) Mum believed that the doses were transposed from 105mg BD where it was meant to be 150mg. Pharmacist mentioned that 105mg was intended based on patient's age/weight (27kg = instructions given were to crush one tablet in 10ml and give 7ml (105mg) BD). Tablets dispensed as opposed to liquid because patient was on a ketogenic diet. GP record was 150mg BD. Hospital pharmacist who checked the discharge letter mentioned that 105mg was intended based on patient's age/weight (27kg = instructions given were to crush one tablet in 10ml and give 7ml (105mg) BD). Mum was giving 150mg tablet crushed in 10ml - Give 7ml BD (mum unaware this had meant she was giving 105mg only). She mentioned that the GP told mum they could only give 150mg tablets (and did not realise that mum was only giving a proportion of the crushed tablet dissolved in water). 	Root Causes

Patient number and discrepancy description	Root Causes
Patient L248	Possible causes:
At discharge the following was written on the discharge letter: - Colecalciferol 3000 units in 1ml liquid was prescribed, dose given was 3000 units via NG OD (colecalciferol 1000 unit dispersible tablets - VIGANOLETTEN). 14 days and continue with GP. Post discharge follow up (8 weeks later) the following was supplied by the community pharmacist: - colecalciferol (for the 60 dispersible tablets dispensed on 11/10/2012). Unknown brand for the 40 dispensed tablets as this was dispensed in a amber bottle. Tablets were brown in colour and did not disperse in water. (15/10/2012). Father will be taking this up with the community pharmacist. Contact the community pharmacist. Contacted 13:00 via telephone 12/2/2013. Community pharmacist mentioned that the colecalciferol would be ordered as a specials and they would specify it as dispersible. As it was a while back, what might have happened is that there might have been an omission of the word dispersible from the specification that was sent to the specials provider. Community pharmacist would have to look into it. The community pharmacist would not order it from the German supplier as specified by the hospital of discharge.	Community pharmacy Transcribing error when ordering the cholecalciferol (forgetting to specify dispersible) on the subsequent second order and supply of what was owing.

Patient number and discrepancy description	Root Causes
Patient T280	Possible causes: -
At discharge the following was prescribed on the discharge letter: - Trimethoprim 50mg/5ml SF suspension, 30mg (3ml), PO ON 7 days and GP continue.	Hospital doctor wrote the prescription in anticipation of possible positive blood result for infection, where the prophylactic trimethoprim dose should not have been on the discharge letter for the GP to continue prior to blood results.
Post discharge follow up 3 weeks later: - Mum called back at 11:56am on 1/11/2012. Patient has completed antibiotics, is well and won't be requiring further supplies of trimethoprim antibiotics.	

4.4.3 Stage 3 A focus group of healthcare professionals' perceptions and experiences of post discharge discrepancies in children post hospital discharge

Six participants who were invited to participate in the focus group all agreed to take part. All participants except one community locum pharmacist had taken part in the severity assessment of unintentional discrepancies identified during the post hospital discharge follow-up. The focus group was multidisciplinary made up of healthcare professionals that worked across the interface of care between hospital and the GP practice and consisted of a GP who worked in South London, consultant paediatrician, consultant hospital pharmacist and research nurse who worked at the same hospital in south London, and two community pharmacists one superintendent and one newly qualified locum pharmacist who also worked for local independent community pharmacies in the South London region.

The transcribed recording was classified into responses based on the questions from the focus group moderator's guide which formed the framework for the analysis. The themes drawn from the analysis were: 1) the healthcare professionals experience of post discharge discrepancies or problems; 2) their process of resolving the discrepancies; 3) Documentation of post discharge problems and interventions by healthcare professionals, 4) their thoughts on who were the best placed profession to continue the patient's medicines after hospital discharge and 5) Any suggestions made about how to reduce problems occurring post hospital discharge. In addition to the themes based on the questions from the moderators guide, the focus

group participants were asked to discuss an example of a potentially moderate severity discrepancy (patient L135), and the details of the discussion and potential solutions

The next section reports on the key points that were raised during the focus group for each theme and also details regarding the discussion around the potentially moderately severe discrepancy example.

1) The healthcare professionals experience of post discharge discrepancies or problems

Each health care profession provided examples of their experience of post discharge discrepancies, and the similarities found were that these experiences discussed by each profession were all initiated at the point where a parent of a paediatric patient had a problem and would consult a healthcare professional for the solution.

The GP experienced a problem in practice where an older sibling of a paediatric patient who was also a child, rang the surgery to explain that the patient's medication had ran out. The older sibling made the phone call as the parents could not speak English. The time was six O'Clock in the evening when the call was received. The GP asked the older sibling to read out the names of the medications and the two medicines were not the routine medications that the GP was familiar with and the GP had no information from previous correspondence. Eventually, after asking the patient's sibling to bring the medications along to the surgery and referring to the paediatric compendium.

"GP: - We had no discharge summary, the child was able to read the names from the bottles of what they had, but of course I have no idea of dosages..... two, although I had the names I had no idea of dosages and I think one of them was medication I wasn't especially familiar with..."

The community pharmacist also experience a problem where the patient had ran out of medication and went to the community pharmacy to request for more. When the records were checked and it appeared that the patient was not expected to have run out this early on and may have been a result of the patient tapering a dose based on consultation with a clinician orally and the changes not communicated to the GP.

"CP: - ... the parent might come to me and say, "I run out of", but why? You are only meant to be on so many, and then we have a conversation with the GP, I've got nothing on my system, the letter I got says this, and that actually does cause problems where it's a verbal instruction"

The hospital nurses' involvement with post discharge problems was when the patients had queries and would call the nurses via telephone who would then consult the consultant and registrar at the hospital who would advise the parents to change their medication dose. These consultations were not always fed back to the other healthcare professionals who cared for the patients e.g. the GP and the community pharmacy.

"RN: - ... many parents will call you if there's a problem and the many times the medication are changed by the nurses, well, after consultation with the consultant or registrar and you should change them over the phone."

The hospital pharmacists were approached by parents who had problems normally when the parents were at the hospital outpatients and would present the pharmacist with a problem at the counter. The problems that were reported by the parent at the counter were issues in relation to the formulations of the medication that the patients would normally get if it differed from what had been written up by the hospital doctor on the handwritten outpatient prescriptions and the hospital pharmacist would amend the prescription and dispense the appropriate formulation.

"HP: Because we know, we'll chat to people at the hatch, and if tablets have been written and they actually want a liquid and in fact the brand was different, for whatever reason, we just change it...."

Another problem that was raised by the hospital pharmacist which was indirectly related to post hospital discharge problems was the challenge of obtaining accurate medication histories for patients at hospital admission. When a medication history was taken at admission, pharmacists were struggling to get records of certain medications that were reported by the parent but were not on the GP's record.

"HP: ... some of the drugs we were struggling to get records of, it's interesting to know where these are in the record, are the regular one offs in some way, something like buccal midazolam, something that's you know these things, irregular, regular meds, where are they....?"

The hospital consultant identified problems that occurred post hospital discharge normally when the patients went to the consultant for a hospital outpatient appointment. Issues that occurred were that the parents hadn't continued on the plan indicated by the consultant, or the patient was taking a different type of medication that they were meant to be on.

"HD: -for example, you know, you'll see a child in the hospital that's presented with epilepsy first time, and you start them on some sodium valproate and usually we would given them a sort of erm, two weeks of a low dose and double it up and off you go and get your repeat prescriptions from the GP. And then you might not see them for maybe another two months or something when they come back to their follow up and say, you know "how much sodium valproate are you taking?" and er not infrequently it's not the amount you expect it to be and it's either that they haven't doubled up or that they've got a completely different formulation or that their GPs decided to put them on tablets rather than liquid or all sorts of things that have, that take you completely by surprise and it's not, it's not what you expect when they, when they come back through the door. I don't know where the changes occur and indeed whether they matter that much certainly in

terms of formulation, got a debate about that in terms of epilepsy, but erm certainly in terms of dose, sometimes they are on half the amount you would expect them to be on because what you had sort of indicated or hopefully indicated in your letter, hasn't happened, why that would be, we often don't know."

The example highlighted that there were problems in relation to continuing with the same medication when a patient changed care settings. Possible reasons provided by the GP at the focus group was to do with cost in terms of medicines that were not routinely prescribed, the GPs would have to go through the PCT for approval.

"GP: - We also have the medicines management committee with the PCT that we also have to liaise with if drugs are not something we would routinely prescribe then it's got to have huge cost implications.."

"HP: Ok, it doesn't matter how much information we put on there almost about where our formulation comes from or anything, you, you'd almost be forced by a PCT (**GP**: PCT initiative effectively yeah) to make a change to it? **GP**:Yeah."

The cause of these problems might not have solely been as a result of the patient's medications being changed by the GP; another possible reason for this would also depend on whether the patient had been admitted to a hospital where another brand of product was used depending on the hospital contracts.

"HP:.... so it makes no difference, what they come in on, they will get the brand we got. The brand will change with the contracts."

2) The focus group healthcare professionals process of resolving the post hospital discharge discrepancies

The healthcare professionals in the focus group also discussed their process of resolving post hospital discharge discrepancies and problems.

The GP would normally consult the parent and make a judgement upon whether to prescribe or to query further depending on if the GP was familiar with the medication and if it was standard routine medication or something that they were not familiar with. If the GP was not familiar with the medication requested, the GP would make an enquiry. The GP felt that there were some drugs where they were not comfortable with prescribing, either because of lack of information or expertise.

".....if I was unhappy, if it was a standard dose of something that appeared to have been changed to a dose that I considered to be a standard dose, I would be happy to probably take verbal confirmation from a parent in a child's case...."

"....It depends, I would have to say it depends on the drug that has been requested and the dose and how uncomfortable I felt with that, what actions I took, and if I was unhappy I would probably try and get hold of the relevant specialty....."

In the scenarios where the GP finds that there is insufficient information, they would try to consult the community pharmacist to see if they could provide

them with further information that may help them. For example the patient may have given the community pharmacist a letter.

"um, if it was a non standard dose of something or it was a drug I wasn't familiar with, I would probably go further to clarify it, whether that was the local pharmacist because he knew the family well they do then to know these chronic families well and he might have a magic piece of paper that I haven't yet seen, or going back to the hospital depends on the patient and the setting I think."

The community pharmacists' role and contributions to solving the problem with the parents involved asking the parent if they had a copy of the discharge letter to see if there was any information the parent had that they and the GP did not have access to. They would ask for documentation if the parent's request for the patient differed to what they had on their systems. The community pharmacist's role was limited by the amount of information and access to clinical information of which the hospital staff and GP may have access to.

"I've been training the parents and depending on the age of the child, also presumably you know conversations you have as well, and erm, in terms of this medicine does this in very simplistic terms and it's very important that you know you have it regularly. And at our end we try to train our patients to you know, give it a week, bring the paperwork to us, you know, tell us what's happening, keep us appraised of what

the treatment plan is, erm and if it doesn't look like what it says on there to have a conversation..."

In hospital pharmacy, when a hospital outpatient prescription was received in the pharmacy outpatients and some information regarding the formulation was missing, for example modified release, the hospital pharmacist would endorse the changes by writing. The pharmacist in hospital did not obtain a replacement prescription, however the community pharmacist stated that in primary care, they would request the doctor wrote a new prescription.

"HP: - Our policy is first line circadin for kids, now that's an MR product. I know half the prescriptions that we get is say melatonin 4 milligrams. Now, we hadn't re-endorsed MR, we knew it had to be MR, it's what they had before, so the prescription just says melatonin 4mg, we dispensed the circadin, which is the MR product, ... But the person who dispensed it hadn't changed the prescription to the MR product"

"GP....And I'd have to send another prescription.... .HP: And you would have to write another prescription, actually formulising what it actually was? I mean the formulation bits, I think we often change at the hatch, i.e. if it's non-specified...."

"HD: So we might not know, I might be sitting in my room thinking, I've dispensed as far as I know, and they are actually going home with something different, and I'll write to the GP, with what I think"

From the discussion regarding hospital pharmacy outpatient interventions made on hospital outpatient prescriptions, the community pharmacist

informed the focus group participants that in community pharmacy, the community pharmacist were only able to intervene by adding directions to a label using their own judgment, however they would require a new prescription if the patient required a different formulation of the medication.

"CP: Yes. The only leeway we have now is in directions, where if the directions aren't quite clear enough, we can add our own, whereas previously, if it said as directed we would have to put as directed, but we can use our judgement in those cases but the product has to be as it is written, we can't suddenly, we can't do generic substitution, we can't do other things that... (51:33)"

3) Documentation of post discharge problems and interventions by the focus group healthcare professionals

The systems that each healthcare professional used to document the post discharge problems and any interventions they made varied depending on their setting and the key issue was that their systems differed, did not assist with aiding communication across the interfaces of care and were not interconnected.

The GP system was described in terms of how acute medication and repeat medications were recorded. One key point from the discussion regarding the GP system was that the medications appearing on the repeat list were the ones that were prescribed and required on a regular basis. Acute medications would not show up on the system and would appear on the child's back-record. At times, when the GP was unsure about whether it was for repeat prescribing or if they felt that they did not have sufficient

information about the medication they would put the medication onto the acute system which meant that if a hospital pharmacist was taking a drug history, the medication under question would not appear on repeat.

"GP: That will be in the past drugs, if it's not prescribed on a regular basis that would be in the past drugs, not the current drugs, because what you don't want is to have anything in the system that might be prescribed inadvertently by somebody, I mean I work in a big teaching practice now but it's not just that it is a safety device I think, the only things that are considered to be regular prescriptions are immediately obvious."

"GP: - There's all sorts of reasons why it might be in the acute system but it won't be put into the repeat system formally until those issues have been resolved."

The community pharmacist expressed that their systems were not adequately built for the purpose of recording interventions and changes and the systems were primarily a dispensing recording with options of viewing a patients previously prescribed medication. The system did have an intervention screen; however it was not easy to retrieve the records.

"CP: - From a community pharmacy point of view our systems are woefully inadequate at allowing us to document and make clinical notes. We need a clinical system that allows us to dispense to actually work much more effectively so we tend to have work-arounds, so we can make notes in the patient's system,

"CP: - but it's not under, it's not re-coded its nothing like that, it will be a note, so we can document and make notes, there are interventions screens as well, so for pharmacy interventions that you know, I spoke to so and so for 10 minutes and there was a problem with the dose and in that respect we can document certain things but in a way where we can then refer back to it, it's not easy to retrieve,...."

Many interventions that were made by hospital healthcare professionals via oral consultations with patients may not have been recorded electronically, or documented. The hospital consultant however, revealed a system had been put in place recently where any consultations with parents and patients were recorded on their electronic prescribing system (EPR).

"HD: - So if I get called by one of my epilepsy patients, I've got quite a lot of epilepsy patients, and I decide to change the drugs over the phone, I will always do a letter back to the GP, and it goes on the EPR system, but I'm not sure what happens across the board for everything that happens."

4) The focus group healthcare professional's thoughts on who were the best placed profession to continue the patient's medicines after hospital discharge

When the focus group participants were asked to discuss their thoughts on who were the best placed profession to continue the patient's medication after hospital discharge, two suggestions were made. The first suggestion was that the GP was thought to be the best place professional to be the gatekeeper of medicines and the second suggestion was that the prescribing

and supply of all unlicensed medicines were to be supplied by the hospital outpatient.

"GP: - In theory the GP should be the gatekeeper of all drugs" "HP: - Well I mean, I have to admit, there's a thing here which is suggesting that all specials come back here into the hospital"

Towards the end of the focus group, the participants felt that the GP was more suited to being the gatekeeper and the best placed profession to continue the patient's medicines after hospital discharge. The reason for the decision may be due to the fact that, although GPs may not have the high level of expertise as the hospital consultants with regards to the specialist medication, however they were clinicians who would be able to make clinical decisions and that the GP surgery would normally be the common recipient of all information for patients who were complex and being seen by several GP specialities.

"HD: Back to your original question, who is the person? The more we discuss it clearly, it's got to be the GP. The issue is how does the GP get the information and how is the communication between the various parties correct? (1:38:43)"

"CP: Particularly with the complex patient who may be going to see several specialties within several different hospitals."

"HD: Yeah, and indeed several different hospitals, you are right. It is certainly for paediatrics, some of our special complex patients may need to be seen at another hospital (1:38:58)."

"GP: There is nobody else really who can have that gate keeping role in medicine as it stands at the moment in this country, I think, that would be my view, not because I'm a GP but it's because logistically, I mean if we could have sort of you know pharmacists attached to practices, you could give the responsibility then, and I would gladly do it (1:39:17)."

"CP: Points I made about, there are two separate jobs there, one is the reconciliation and the other is prescribing decision. There in an ideal world perhaps. But certainly, as a common recipient of information about patients, there is only one place. (1:39:37)."

The participants decided through discussion that it seemed like the GP was the most suited profession to continue the patient's medication. There was still another question of how the information should be communicated to them. The community pharmacist also found that there were actually two roles within the continuing of a patient's medication, the prescribing clinical decision and the medication reconciliation process.

5) Any suggestions made by the focus group participants on how to reduce problems occurring post hospital discharge

The final question (prior to discussing the example discrepancy) posed to the focus group participants were any suggestions on how to reduce the

problems occurring post hospital discharge and there were several suggestions made throughout the focus group based on the problems discussed.

The GP suggested that when the hospital professionals were questioning patients to establish a medication history to ask for their repeat prescription slips.

"GP: But even the vision repeats, you know if it's on their standard repeat prescribing list whether they are a child or an adult, the right hand sheet will have their repeat prescriptions, as the practice understands them on that sheet. So it's another source of information for you and if we could all try and train the patients to use this, um I mean my first question in A&E with a complicated patient is have you got your repeat slip, as I'm a GP and I know it exists in your bag and often they will get their wallet out and take it out and give it to me. Which means that at least I got some idea where I'm coming from (40:38)."

"GP: Certainly if need brand name prescribes, you need to do to explain why, if you've got any hope of actually getting it the other end after your first description. (1:31:52)"

Suggestions for reducing discrepancies and problems in relation to community pharmacy were that it would be advisable for complex patients to stay with one community pharmacist for continuity and consistency.

"GP: I do encourage my complex patients who haven't got..., "do you have a regular pharmacist?" very often, particularly picking up their

own prescriptions and say why don't you talk to x if they say "Yes I have" because they would be happy to sort this out for you. (1:39:50)" "CP: Same pharmacy that you are comfortable with, because quite often we're shooting blind. We don't have the clinical records and in a court of law, you'd be judged against your peers who are working in a similar environment. So I wouldn't be judged against a hospital pharmacist. I'd be judged against my other peers in the community and so that phrase of "if in doubt check it out" is always the best mode of memoranda, but having that complete management plan in terms of, these are all the medicines that we, that they should be on...."

Suggestions of how to improve the information provided by the discharge letter was also made by the GP in terms of what information should be on it and suggestions on details: -

"GP: Perhaps the highlighting of, particularly if you've got a complex prescription, highlighting of either key drugs or just drugs that have actually changed their doses, would mean that people's eyes would be and maybe some IT way of incorporating that (28:30).

Community pharmacist have also expressed that having the discharge letters sent to them would help with reducing problems as often they had to dispense prescriptions with little information. In current practice they would ask to see the patient's discharge letter if they were querying hospital dose changes.

"That process we found, seems to work, because erm now the patient's know or the parent's know that you know I'm going to be 267

asking for a copy if it doesn't match what is on my computer because I know that if it doesn't match the GPs computer, its going to delay everything, so it's a key message, it has to happen every time that you know the pharmacist is there as well because they are going to be giving out the drugs, erm and in our case, we are also requesting it as well, erm because that allows us the opportunity to have the conversation. (25:08)"

Focus group participant discussion of the possible causes and solutions to an example of a moderately severe discrepancy

The focus group were given the following example of a moderately severe discrepancy and were asked to comment and discuss the possible root causes and potential solution.

Example post discharge discrepancy

Patient L135

Male Neurology patient aged 5

At discharge the following was written on the discharge letter: -

- 3. Omeprazole 10mg/5ml liquid. 40mg PEG OM, Continue with GP.
- Trihexylphenidyl 5mg/5ml liquid. 6mg PO TDS 8am, 2pm, 8pm.
 POD/TTA.

Post discharge follow up 3 weeks later: -

- 3. GP record Omeprazole 20mg PEG OM .
- 4. GP record Trihexylphenidyl 3mg PO TDS

Dad stated that he was aware that the GP was not up to date and would just follow the hospital recommended dose.

The focus group participants discussed and suggested the following possible causes of the discrepancy: -

The GP felt that the dose for the patient's omeprazole was very high for the patient and that this was high dose even for adults. In practice, without some information regarding the background and rationale behind prescribing the GP would not be happy to prescribe. The GP also suspected that the surgery may not have received the discharge letter.

"GP: Well the causes is going to be that the doctor hasn't got a copy of the up to date medication, I suspect, and 40mg of omeprazole even in an adult is a big dose.

HD: it's an unusually high dose"

"......GP: I think if I thought the reason was good enough. So that would depend on the text and the letter that came with that request, I might take responsibility for prescribing 40mg of omeprazole in a small child. I'm not saying, I would always do so. (1:07:36)."

From the community pharmacist's perspective, an example that the pharmacist had experienced personally was that there were times where a patients dose had changed in hospital as the one in the example and that they would present the document to back the change in community pharmacy.

"CP: - The other side to that, actually is the experience that I had where erm a child was on errrr omeprazole 10mg for a while, er, and we had the letter saying its gone up to 20, but it had been put as repeat at 10 and so when the requests goes in, although, I mean we tend to erm make a copy and submit that with the request, er so that they, you know the letter is there in case you know for whatever reason it's not available erm you know it's quicker and so our main practice, the receptionist would say, "yes the doctor would need to see this"

The participants discussed that there were multiple possible reasons for the discrepancy such as, the GP not comfortable with the prescribing or not receiving the paperwork. The possible causes discussed by the participants differed from the Root Cause Analysis investigation that was carried out for

the patient which found that the parent was the cause, as the parent did not consult the GP for review and went to the GP to request further supplies of medication. However this discussion adds to the possible healthcare professional reasoning on not changing the dose according to the hospital discharge letter dose.

4.5 Discussion

The results suggest that discrepancies and problems occur between the interfaces of care when a child is discharged from hospital back to their GP. The incidence of the patients who had at least one discrepancy of any type was 36.8% (95% Confidence Interval 29.8% - 43.8%), and the incidence of potentially moderately severe unintentional discrepancies of patients was calculated to be 7.6% (95% Confidence interval 1.1% - 16.0%). These values however take into account only the parents and patients who were approached by the research team, gave written consent, and were not lost to There were no published studies reporting an incidence of follow up. discrepancies in medicines after a paediatric patient was discharge, the proportion of discrepancies in this study is similar to the proportion of medication discrepancies that occur in paediatric patients at admission. A similar post discharge follow up study of older adults aged 65 years and conducted 24-72 hours post discharge reported a lower discrepancy rate of 14.1% (Coleman et al 2005).

The qualitative analysis of the follow up comments made by parents and patients revealed that patients experienced problems relating to the hospital,

GP, community or the parent, but also comments on interventions that were made to address these problems were also provided by the hospital, GP and parent. However from the follow-up, parents only reported services that community pharmacists provided such as the prescription collection service or home delivery.

The root cause analysis undertaken by the research pharmacist independently revealed that all the moderate discrepancies in doses were caused by a breakdown or delay in communication between care providers. One of the discrepancies from the root cause analysis was discussed by the focus group as an example found that there might possibly be other reasons and causes to discrepancies and provided another perspective.

The focus group of healthcare professionals who worked across the interface of care between hospital and community pharmacy also highlighted that there were issues with communication and this issues were discussed and explored in further depth. The multidisciplinary composure of the focus group helped with revealing the communication problems for example the community pharmacy found that patients were running out of medications a bit earlier than usual and the research nurse picking up that it may be a result of the nurses and doctors in the hospitals asking the parents to taper doses during telephone consultations.

In summary, the study shows that some paediatric patients in England who are discharged and on long term medications currently experience post hospital discharge discrepancies, a proportion which are moderately severe

if not dealt with. Post discharge problems in addition to it also occur, however from the follow up comments; these problems are resolved by the parent, GP and hospital.

Further work and research is required in this patient group to establish an intervention to prevent post discharge discrepancies from occurring. The focus group findings have shown that the interventions that will help reduce or prevent post hospital discharge medication discrepancies may need to involve all healthcare professionals that the parents have contact with. The intervention should facilitate the communication of sufficient information to GPs of any changes, reviews, dose adjustments that occur at any point of a patient's care.

In addition to a post discharge intervention aimed at preventing post hospital discharge issues, the study findings suggest that community pharmacies may need to implement a service to review paediatric patients who have recently been discharged from hospital as no parents commented or disclosed any clinical interventions that community pharmacists made. Nearly all of the follow ups were conducted by reviewing the patient by talking with their parents who were managing their child's medication, this would mean that many children would not be able to use the Medicines Use Review service in community pharmacy. The Medicines Use Review (MUR) service has to be a service conducted on a patient and not via their carer, hence future work is required to explore if a possible modified version of the

MUR which will allow the review to be conducted on a patient via their parents acting on their behalf is feasible.

Limitations

The post hospital follow up study only included parents and patients who were able to speak English due to resource limitations, and the focus group results highlighted that the parent had problems with children whose parents could not speak English.

4.6 Conclusions

This first UK based follow up study of parents of paediatric patients post hospital discharge revealed that this patient group are at risk of moderate harm when discrepancies occur between hospital discharge medication lists and GP further medication supplies. Problems that may not have manifested itself as a discrepancy also occur across the interfaces of care with parents, GPs and hospitals revealed as the people who intervene to address the problem, without any consistency. Community pharmacy interventions were not discussed or revealed by comments from parents other than the prescription collection service. The focus group of healthcare professionals suggests that the problem behind post hospital discharge discrepancies is issues with communication of information between the interfaces of care and the staff and any future intervention to reduce this will require a multidisciplinary approach involving GPs, hospital healthcare professionals and community pharmacists.

Chapter	5
---------	---

In 2007, one of the World Health Organisation's patient safety solutions was to assure that patients' medications were accurate at transitions in care (WHO 2007). The report suggested that health-care organizations put in place standardized systems to collect and document information about all current medications for each patient and provide the resulting medication list to the receiving caregiver(s) at each care transition point (WHO et al 2007). In the UK, the National Patient Safety Agency and National Institute for Health Care Excellence produced guidance on medicines reconciliation for hospitalised patients at hospital admission; however children under the age of 16 years of age were excluded from the guidance.

In the past, medication errors and the harm of patients had already been a concern worldwide, since the US National Academy of Medicine "To err is Human" report of 1999. As a response to the report, healthcare organisations in the developed countries set up organisations to put reporting systems in place to identify and learn from errors (Kohn et al 2000). Since the report, another initiative by the US Institute of Healthcare Improvement set up a 100,000 lives campaign in 2006 followed by its successor the 5 million lives campaign. The former campaign suggested medication reconciliation as a strategy to reduce "preventable adverse events" (IHI 2008).

Since the report, there have been research studies of the incidence of medication administration errors in hospitalised children (Wong et al 2004; Ghaleb et al 2006) and also a studies which evaluated the impact of electronic prescribing on hospitalised children in the UK (Jani et al

2008;2010). As the NICE guidance on medication reconciliation did not cover children, a neurosurgical ward in Birmingham children's hospital investigated the incidence of medication discrepancies that occurred and found that half the discrepancies identified in children who had a history of chronic medications prior to admission were at risk of a adverse clinical outcome in the absence of medication reconciliation.

As there was a gap in the evidence of whether children were at risk of medication discrepancies and required medication reconciliation at hospital admission in England, a review of the literature funded by the UK Neonatal Paediatric Pharmacist's Group (Chapter 1.5 of this thesis), by Huynh et al (2013a) was conducted to find relevant published studies. At the time of the review, there were only ten studies, of which one study was UK based by Terry et al (2010), which confirmed the need to establish the epidemiology of medication discrepancies in children across the interfaces of care and if medication reconciliation was required.

The aims of the studies were to identify the epidemiology, causes and clinical significance of discrepancies that occurred in hospital admission (building on the study by Terry et al (2010) in Birmingham), discharge and post hospital discharge from hospital to their GP for children specifically. Three studies were carried out, each of which adopted a mixed methodological approach where qualitative and quantitative methods were used to find specific answers as appropriate.

The studies in this thesis made the following findings which made an original contribution of knowledge into the epidemiology of medication discrepancies and need for medication reconciliation: -

- Paediatric patients were at risk of harm during the transitions in care, from hospital to home.
- The observational studies found that patients experienced discrepancies at hospital admission, discharge and even post hospital discharge.
- Potentially harmful discrepancies observed at admission and discharge demonstrated the need for an intervention such as medicines reconciliation.
- In paediatrics, when given the choice, GPs were only contacted to confirm the patient's medication history. In practice, pharmacists need to consult more than two sources of information to establish the patient's medication history and reconcile the medications
- The findings from the post hospital discharge follow up study revealed that discrepancies and problems occurred between hospital discharge and GP possibly due to problems with communicating the information regarding changes to a patients medication made by one of a team of healthcare professionals who have an input into the patients care.

 Medication reconciliation in children involves many healthcare professionals and a team approach may be required to reduce discrepancies that occur along the interface of care.

At hospital admissions, children admitted to hospitals across four geographically different areas in England all experienced unintended medication discrepancies. The incidence for children on chronic medications who had at least one unintended discrepancy was 45% of which 32% had the potential to cause a moderate or severe clinical outcome across England. This incidence was higher when compared with the incidence of patients with at least one unintended medication discrepancy at one hospital site in Canada being 22% (Coffey et al 2009). The study had reported that a medication reconciliation intervention was being implemented, which may have had an effect on observing the actual incidence of discrepancies. An adult study that observed unintended medication discrepancies by Cornish et al (2005), reported an incidence of 53.6% based on the data of a Canadian teaching hospital which was higher than what was observed in the multisite admission study in England.

The admission study (Chapter 2), indicated that not one source of information provided a complete medication history list for a paediatric patient when the pharmacists used the West Midlands Medication Reconciliation form (Appendix B). The parent/carer interview was the most complete source of information but not one hundred percent complete in comparison to the pharmacist's recommended therapy, followed by the GP and the least were the patient's own drugs brought in. A Canadian study that

measured the completeness of information source used to prepare a best possible medication history for children also found that the parent/carer interview was the most complete; however they found that community pharmacists provided the second most complete source of information (Dersch-Mills et al 2011. The Canadian study did not involve contacting the family physician in primary care, however it utilised information from the patient's preceding six months of activity recorded in a provincial prescription database (Dersch-Mills et al 2011). The Canadian study found that the prescription database was the least complete source of information as it was limited by system downtimes and pharmacies that do not upload all prescription data and in addition to this, the source did not reflect dosage adjustments discussed orally by the physician and patient (Dersch-Mills et al 2011). The admission study in the thesis, did not use GP summary care records which were not available to hospital pharmacists across all four of the study sites at the time. However, from the Canadian study, it has been found that prescription databases may not be able to record or reflect the patient's current medication list.

The discharge study conducted as part of this thesis was the first known UK study to assess the prescribing accuracy of hospital discharge letters which found one in three discharge letters out of the 142 letters reviewed prospectively had a discrepancy. The discharge study by Ling et al (2009), found retrospectively that out of 28 discharges reviewed, 12 (43%) had a discrepancy between the best possible medication discharge plan which was

defined retrospectively, against the medication that the patient was discharged on.

The post discharge follow up of children at the point of obtaining further supplies of their medications revealed that approximately 1 in 5 had an unintended discrepancy of which 1 in 13 had potential to cause moderate There were no discrepancies that were considered as severe harm. harm. The method used to observe post discharge discrepancy was different to that of studies of adults aged 65 years or over which followed up patients 24 - 72hours after hospital discharge (Coleman et al 2005). Problems that were reported via the oral accounts by the parents via telephone or home visits were recorded and later categorised. The data collection method for the adult study utilised a pre-determined medication discrepancy tool, which classified the post discharge discrepancies into types. The findings of the post discharge follow up study in the thesis with regards to the problems were qualitative and classified into themes, whereas the findings from the adult study from Coleman et al (2005) were quantitative and determined as 50.8% patient related factors and 49.2% system associated.

The post discharge follow up of children identified problems that occurred when information was transferred from the hospital discharge letter to the GP practice. No other study known has explored the reasons behind why discrepancies were occurring. The CQC reported in the survey that GPs found that around half of discharge letters were received in time to be useful and also found that the same proportion were not accurate (CQC 2009). The focus group of healthcare professionals from different

professions provided an opportunity for them to meet together and discuss the specific issues behind post hospital discharge discrepancies. The focus group revealed that GPs required not only the medication list from a discharge letter, but also specific instructions and explanations of circumstances where patients were to stay on a particular brand of product. It was also observed that consultations between hospital healthcare professionals and patients that did not involve the GP or community pharmacists caused problems. This was the first known inter professionals together to discuss medication reconciliation in the context of post hospital discharge in children.

5.1 Suggestions for improving and standards for medication reconciliation upon hospital admission, and implementing interventions for post discharge in children

Based on the findings from the studies, the following recommendations for implementing medicines reconciliation interventions across the interface of care in children are: -

- Paediatric patients who are on long term medications should receive medication reconciliation when they transfer between care settings
 e.g. from GP to hospital(s), hospital to hospital, hospital to GP
- Health care professionals involved with taking a medication history from a child at admission should consult more than one source of information and should start with their parents

 Any interventions or changes made by any healthcare professional need to be recorded and communicated to other healthcare professionals responsible for the paediatric patient, the GP and community pharmacist

This thesis supports the view that medication reconciliation is a requirement to ensure that patients are not put at risk of potential clinical harm associated with non-reconciliation at hospital admission and discharge. Hospital pharmacists are considered the most appropriate profession to conduct medication reconciliation (Reeder and Mutnick 2008; Strunk et al 2008), and as the survey of paediatric pharmacists shows, medication reconciliation is already taking place in paediatric hospital settings (Huynh et al 2013b). The focus group of pharmacists, who took part in the admissions reconciliation study, have expressed that junior pharmacy staff were unfamiliar with medication reconciliation in children and may need further training. Nurses have been described by studies as a professional group that have been and can be involved in medication reconciliation, either in collaboration with a pharmacist, taking control of the process of obtaining the medication history but checking with the pharmacist if they were uncertain if the discrepancy was intended or not intended. This has been studied in the US (Feldman et al 2012). Nurse staffing levels in England may not be able to support medication reconciliation since a study recently has reported that due to low staffing levels, nurses have had to leave some care work undone (Balls et al 2013). Hence, to implement and assign the role of medication reconciliation to nurses currently in hospital will is unlikely to be feasible. Pharmacy

technicians, have also been considered as a profession to involve in conducting medication reconciliation at hospital admission, with the view that they can decrease medication discrepancies in the Netherlands where pharmacist numbers nationally have been low, (van den Bernt 2009). The study focus group participants in this thesis suggested that the technicians in the England should only be involved in obtaining the medication history, with the clinical aspect of resolving the discrepancies left to the pharmacist (Chapter 2 section 2.4.4).

5.2 Strengths and limitations of the thesis

The thesis aimed to determine the epidemiology and quantifying the incidence of medication discrepancies that occurred at the interfaces of care. The designs of the studies conducted in this thesis relied on primary data collection and included reviewing admission medication orders, discharge medication orders and post discharge medication lists. Pharmacoepidemiology studies of medication errors that involve primary data collection have been considered very time consuming and labour intensive (Strom ed. 2005). This thesis was designed, conducted and managed by the PhD candidate with the support of academic and clinical supervisors, and grants have been used to allocate resources. This has taken three years. An alternative approach for studying medication discrepancies in children upon hospital admission would have been to conduct small scale medication reconciliation data collection across many UK hospitals at hospital admission and discharge with standardised data

collection forms, however, this would also require staff to oversee the process and train the staff.

The thesis study designs used a mixed methodological approach of quantitative and qualitative methods. Without the collection and interpretation of the qualitative information from the studies in the thesis, for example the descriptive accounts of problems encountered by parents post hospital discharge, which would not be identified as a discrepancy, these issues would remain unknown.

The study has the following limitations. The thesis consisted of an observational study which aimed to establish the epidemiology of medication discrepancies at the point of hospital admission, discharge and post discharge in children. It was not designed to stratify and compare the incidences of medication discrepancies per patient speciality or specific medication class. As this study was not concentrated on observing a specific specialty or medication class, this meant that it covered a majority of the patients who were on long term medication.

The study designs in this thesis was observational and non-interventional, hence the thesis was only able to establish the epidemiology of medication discrepancies.

During the course of the data collection for the multisite admission study, although the prescribing doctors were unaware of the study, the parents and carers were aware that the study pharmacists were collecting data which may have an effect on the outcome of the parent interview.

The post discharge study required parental consent for follow up purposes and both parents and the patients were given patient information leaflets. Having to read through the information leaflets and obtain written consent may have had an effect or barrier in recruitment, however the study team did not have permission from the Research and Ethics committee to record details of reasons for refusal to take part in the follow-up.

One final limitation is that the study was conducted in one country only and not internationally. This approach was adopted as healthcare systems vary from country to country. The principals and methodology of finding the incidence of discrepancies at each interface of care, admission, discharge and post discharge adopted by this thesis may be adapted to measure similar outcomes in other countries to assess if medication reconciliation is required in children.

5.3 Recommendations for clinical service development

This thesis has highlighted many issues and potential gaps in service provisions which may need to be addressed to ensure that preventable harm due to transitions in care is minimised and patient care is improved in children.

From the admission study, it has been highlighted that GPs did not have a full list of medications that a child was taking. There were two possible reasons behind this, one being the supply of a medication not available in the GP surgery system/formulary or the GP not being up to date with changes made to the discharge letter. One recommendation to improve this is to ensure that the GPs are informed of a patient's admission and

discharge from the hospital and ensure that any changes are accounted for. For hospitals that may not have a designated section in the drug chart to record medication reconciliation, the evidence built from developing a pilot intervention an pathway suggests that junior pharmacy staff in paediatrics may benefit from being trained to use a pathway and the importance of documenting the origins of the sources of information.

In order to improve medication reconciliation service provision for children, it is recommended that the NICE guidance on medication reconciliation at admission expands to include children. The approach of how to conduct medication reconciliation in children differs to adults as to date the GP's record is not always reflective of the patient's entire medication record that is updated. The definition in the guidance may also need to be expanded or an alternative definition required for paediatrics to include "formulation", expanding on the general term "full and current list of medicines" cited from the National Prescribing Centre guidance on medication implementation (National Prescribing Centre 2013).

At discharge, although discharge letters are accurate in reflecting the patient's medication at discharge, the information may not be clear to the GP in terms of where in the process this has changed. GP surgeries who were interview have also revealed variances in their review procedure with nonclinical staff involved in some stages of the update of the patient's records.

Community pharmacy has the potential to help reduce discrepancies and may have experience in doing so for adults via the reformed Medicines Use Review (MUR) which include recent hospital discharge patients as a

target group. However, there is a problem with access to a MUR for children due to the direction stating that a MUR must be conducted via consultation with the patient. This means that the review is limited to a child who has the capacity to consent and have a discussion about their medications with a pharmacist (Pharmaceutical Services Negotiation Committee 2013). Hence, children who do not have the capacity to consent, and some who may have the capacity to consent may not be confident to "fully engage in discussion with a pharmacist." This thesis suggest that either further work into a separate post discharge reconciliation review intervention should be designed for community pharmacists or an alternate suggestion would be for an exception to be made in the current regulatory framework to permit an MUR to be conducted for a child by consulting the parent or carer.

Post hospital discharge follow up comments and the focus group of healthcare professionals (in Chapter 4 of this thesis) highlighted that the community pharmacist suggested that the patient should stay with the same community pharmacy to ensure consistency in care. Findings from a recent review of pharmaceutical services by Wilson and Barber (2013), also found that patients in Scotland used the term "named pharmacist" to describe the relationship between patient and the pharmacist. Patients who were involved in the review also described that they want continuity and consistency of professional input and care from an individual pharmacist. This review involved patient groups but did not indicate if the views of parents of paediatric patients were included in this consultation. (Wilson and Barber 2013).

288

To address the issue of medication discrepancies and problems that occur as a result of parent communication with hospital consultants and other healthcare professionals (e.g. over the telephone), what may help is to implement a patient held diary of medication related consultations. The medication passport developed by County Durham and Darlington, and Imperial College Healthcare NHS Trust principally with older patients in mind may be a template that could be considered for adaptation for use in paediatrics (Royal Pharmaceutical Society 2012). This suggestion of a patient held diary may help with children who may be cared for by more than one hospital and/or consultant who may not be aware of each other or be able to communicate between hospitals. Situations where parents have experienced conflicting information from two different doctors based at two different hospital sites as described in chapter 4 of the thesis (page 220) may be avoided if such a patient held diary is implemented. Before such a service can be provided, it would be important to establish if a diary would be feasible for all parents depending on their understanding of medication, doses and dosage forms. It was highlighted from pharmacists and GPs from the focus groups in chapter 2 and 4 of this thesis that there were patients who only knew the mode of administration for the medications in millilitre volume and also children who came from families where the parents/carers could not speak English. The accessibility of any future service provision that involves the parents will require assessment of suitability and effectiveness.

289

From the point of post discharge to GP surgery review, it has been suggested from the post discharge focus group (chapter 4 of thesis) that it would help if hospital discharge letters highlight any changes that occur at hospital discharge. The Royal Pharmaceutical Society guidance in transitions in care (2012) highlighted that the details of medication changes and medication recommendations for example brand names were included in the recommended core content of discharge letters (Royal Pharmaceutical Society 2012). Further research into GP review and interpretation of discharge information may be required.

A final point and recommendation for clinical service development for medication reconciliation is for GPs to be sent details of any consultation between a patient and over the hospital doctor over the phone that results in a change of direction. The studies in this thesis have examples of where a patient's medication directions had changed and not been updated on the GP system. This information should be communicated based on the Royal Pharmaceutical Society guidance of core content of discharge letters, with adaptations to indicate the change in a setting outside an inpatient hospital setting and outside primary care.

In summary of the recommendations for clinical service development based on the thesis findings, the key issues were: -

- Ensuring paediatric patients admitted to hospital receive appropriate medication reconciliation
- An intervention is required from community pharmacy to review paediatric patients as they would in adults who receive medication

290

reconciliation through the existing MUR which is not accessible to children. For this to be effective, the MUR service may need to be amended to permit pharmacists to conduct the review of a child via the discussion with parent or carer, which is currently not permitted.

- It is recommended and suggested the feasibility of parents carrying a patient held record for their child similar to a medication passport should be explored in the future.
- A further study may be required to assess why GPs have continued to have issues with interpreting the information on the discharge letters in observing the GP review procedure.
- It is suggested that any consultation that occurs with a hospital consultant whether outpatient or telephone consultation which results in a direction change should be communicated to the GP in a timely fashion and within a suitable time frame.

5.4 Suggested future areas for further study

From the current thesis, it is now known that hospitalised children in England are at risk of harm in the absence of reconciling medications across the interface of care. Further research is required in this field to address the following unanswered questions that arise from the results: -

- Research into how an initial drug chart is written up by the hospital doctor and reasons behind their decision
- Observations in out of hours admission and discharge procedures

- Research into designing a form which can be used to record consultations which lead to a change in the medication a patient is taking with adequate but not excessive information in discharge letters.
- Exploring opportunities for community pharmacists to do medication reviews of recently discharged paediatric patients which will involve interviewing parents and carers for children who don't have the capacity to consent and manage their long term medications

5.5 Conclusion

The three studies have shown that children in England may be at risk from a preventable adverse event as a result of medication discrepancies occurring when a patient is admitted to hospital, at the point of discharge and after they have been discharged. Healthcare professionals and parents all contribute to help solve the discrepancies and problems that occur across the interface of care; however communication problems are at the heart.

This thesis is a contribution to new knowledge and the following conclusions summarise the key findings: -

 Children in England are at risk of harm caused by medication discrepancies observed occurring at the following transition points: hospital admission, discharge and post hospital discharge.

- At each transition point, a clinical assessment has been used to find the potential clinical consequences of these discrepancies.
 Potentially harmful consequences have been estimated.
- Medication reconciliation is required at each of these transition points for children
- Further work is proposed to design interventions to reduce this patient safety risk

In conclusion, this thesis demonstrates that medicines reconciliation is required in children as well as adults, as one of the interventions that may contribute to reducing harm. This finding will not totally eradicate problems affecting children's health and outcomes or remove all patient safety issues, however it may help reduce harm. Although this study focuses on medication discrepancies and reconciliation it is an important contribution towards the safety of patients for the future of healthcare in England. As the most recent report "Improving the Safety of Patients in England" from Professor Don Berwick suggests that "While "zero harm" is a bold and worthy aspiration, the scientifically correct goal is "continued reduction" (Department of Health 2013).

References

Accreditation Canada. Required Organizational Practices 2012. [online]. Available from:

http://www.accreditation.ca/uploadedFiles/ROP%20Handbook.pdf [Accessed 23rd July 2013].

Agrawal, A., Wu, W., Khachewatsky, I. 2007 Evaluation of an electronic medication reconciliation system in inpatient setting in an acute care hospital. Studies in Health Technology and Informatics, 12(2), pp. 1027-1031.

Agrawal, A., Wu, W.Y. 2009. National patient safety goals. Reducing medication errors and improving systems reliability using an electronic medication reconciliation system. Joint Commission Journal on Quality & Patient Safety, 35(2), pp. 106-115.

Alldred, D.P., Petty, D.R., Standage, C., Zermansky, A.G., Raynor, D.K., Strickland-Hodge, B. 2010. Medication discrepancies and errors postdischarge from hospital: a pilot evaluation. International Journal of Pharmacy Practice, Suppl. 1, pp 20.

Balls, J.E, Murrells, T., Rafferty, A.M., Morrow, E., Griffiths, P. 2013 'Care left undone' during nursing shifts: associations with workload and perceived quality of care. British Medical Journal: Quality and Safety. [online]. Available from: - <u>http://qualitysafety.bmj.com/content/early/2013/07/08/bmjqs-2012-</u> 001767.full.pdf+html. [Accessed 10th August 2013]

Bates, D.W., Cullen, D.J., Laird, N., Petersen, L.A. Small, S.D., Servi, D., Laffel, G., Sweitzer, B.J., Shea, B.F., Hallisey, R., Vliet, M.V., Nemeskal, R., Leape, L.L. 1995. Incidence of Adverse Drug Events and Potential Adverse Drug Events: implication for prevention. Journal of the American Medical Association, 274, pp. 30-34.

Bédard, P., Tardif, L., Ferland, A., Bussières, J.-F, Lebel, D., Bailey, B., Girard, M., Lachaîne, J. 2011. A medication reconciliation form and its impact on the medical record in a paediatric hospital. Journal of Evaluation in Clinical Practice, 17(2), pp. 222-227.

Braun, V., Clarke, V. 2006 Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), pp. 77-101.

Caligiuri,C., Staub, M., Galloway L, Blydt-Hansen, T. 2009. A computerized pharmacy generated medication reconciliation for transfer from the intensive care unit reduces discrepancies and order writing time. Canadian Journal of Hospital Pharmacy, 62, pp 345.

Campbell, F., Karnon, J., Czoski-Murray, C., Jones, R. 2007. A systematic review of the effectiveness and cost-effectiveness of interventions aimed at preventing medication error (medicines reconciliation) at hospital admission. [online]. Available from:

http://www.nice.org.uk/nicemedia/live/11897/38591/38591.pdf [Accessed 23rd July 2013]

Care Quality Commission. October 2009. National study. Managing patients' medicines after discharge from hospital. [online]. Available from: http://www.cqc.org.uk/ db/_documents/Managing_patients_medicines_after_discharge_from_hospital.pdf [Accessed 13th December 2010].

Carter, M.K., Allin, D.M., Scott, L.A., Grauer, D. 2006. Pharmacist-acquired medication histories in a university hospital emergency department. American Journal of Health-System Pharmacy, 63(24), pp. 2500-2503.

Child Health and Maternity Partnership. March 2011. Fundamentals of Commissioning Health Services For Children. [online]. Available from: <u>www.chimat.org.uk/resource/view.aspx?RID=106744</u> [Accessed 23rd July 2013].

Coffey, M. 2009a. Medication reconciliation: Coming to a hospital near you. Paediatric Child Health, 14, pp. 76-77.

Coffey, M., Cornish, P., Koonthanam, T., Etchells, E., Matlow, A. 2009b. Implementation of admission medication reconciliation at two academic health sciences centres: Challenges and success factors. Healthcare Quarterly, 2009b, 12, pp.102-109.

Coffey, M,, Mack, L., Streitenberger, K., Bishara, T., De Faveri, L., Matlow, A. 2009c. Prevalence and clinical significance of medication discrepancies at pediatric hospital admission. Academic Pediatrics, 9, pp. 360-366.

Coleman, E.A., Smith, J.D., Raha, D., Min, S.-J. 2005. Posthospital Medication Discrepancies. Archives of internal medicine, 165, pp. 1842-1847

Collins, D.J., Nickless, G.D., Green, C.F. 2004. Medication histories: Does anyone know what medicines a patient should be taking? International Journal of Pharmacy Practice, 12(4), pp. 173-178.

Cornish, P.L., Knowles, S.R., Marchesano, R., Tam, V., Shadowitz, S., Juurlink, D.N., Etchells, E.E. 2005. Unintended medication discrepancies at the time of hospital admission. Archives of Internal Medicine, 165, pp. 424-430.

Dean, B., Barber, N., Schachter, M. 2000. What is a prescribing error? Quality in Health Care, 9, pp. 232 – 237.

Dean, B.D., Barber, N. 1999 A validated reliable method of scoring the severity of medication errors. American Journal of Health-System Pharmacy, 56, pp. 57-62.

Dean, B. 1993. A transatlantic study of medication system errors in hospitals. Thesis (MSc.), University of London.

Department of Health. 2006. Child Health and Maternity Services Branch. Transition: getting it right for young people. [online]. Available from: <u>http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/d</u> <u>ocuments/digitalasset/dh_4132149.pdf</u> [Accessed 28th December 2012].

Department of Health. 2007. National Service Framework for Children Young People and Maternity Services: core standards [online]. Available from:

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4094329 [Accessed 24th July 2013]

Department of Health. 2011. Transforming Community Services -Demonstrating and Measuring Achievement: Community Indicators for Quality Improvement. [online]. Available from: -<u>http://www.dh.gov.uk/prod consum dh/groups/dh digitalassets/documents/d</u> <u>igitalasset/dh 126111.pdf</u> [Accessed 23rd July 2013]

Department of Health. 2013. A promise to learn – a commitment to act. Improving the Safety of Patients in England. National Advisory Group on the Safety of Patients in England. [online]. Available from: -<u>https://www.gov.uk/government/publications/berwick-review-into-patient-</u> <u>safety</u> [Accessed 10th August 2013].

Dersch-Mills, D., Hugel, K., Nystrom, M. 2011. Completeness of information sources used to prepare best possible medication histories for pediatric patients. Canadian Journal of Hospital Pharmacy, 64(1), pp. 10-15.

Feldman, L.S., Costa, L.L, Feroli, R., Nelson, T., Poe, S.S, Frick, K.D., Efird, L.E., Miller, R.G. 2012. Nurse-Pharmacist collaboration on Medication Reconciliation Prevents Potential Harm. Journal of Hospital Medicine, 7, pp. 396-401.

Forster, A.J., Clarke, H.D., Menard, A., Dupuis, N., Chernish, R., Chandok, N., Khan, A., van Walraven, C. 2004. Adverse events among medical patients after discharge from hospital. Canadian Medical Association Journal, 170(3), pp. 345-349.

Gardner, B., Graner, K. 2009. Pharmacists' medication reconciliation-related clinical interventions in a children's hospital. Joint Commission Journal on Quality and Patient Safety, 35, pp. 278-282.

Ghaleb, M., Barber, N., Franklin, B., Wong, I.C. 2010. The incidence and nature of prescribing and medication administration errors in paediatric inpatients. Archives of Diseases in Childhood, 95, pp. 113-118.

Ghaleb, M., Barber, N., Franklin, B., Yeung, V., Khaki, Z., Wong, I. 2006a. Systematic review of Medication errors in paediatric patients. The Annals of Pharmacotherapy, 40, pp. 1766-1776.

Ghaleb, M., Wong, I. 2006b. Medication Errors in Paediatric Patients. Archives of Diseases in Children: Education and Practice edition, 91, pp. ep20-ep24.

Gleason, K.M., McDaniel, M.R., Feinglass, J., Baker, D.W., Lindquist, L., Liss, D., Noskin, G.A. 2010. Results of the Medications At Transitions and Clinical Handoffs (MATCH) Study: An analysis of medication reconciliation errors and risk factors at hospital admission. Journal of General Internal Medicine, 25(5), pp. 441-447.

Gleason, K. M., Groszek, J. M., Sullivan, C., Rooney, D., Barnard, C., and Noskin, G. A. 2004. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. American Journal of Health-System Pharmacy, 61, pp. 1689-1695.

Grimes, T. Duggan, C., Delaney, T. Graham, I., Conlon, K., Jago-Byrne, M., O'Brien, P. 2010. Medication reconciliation on discharge from acute hospital care in Ireland. Pharmacoepidemiology and Drug Safety, 19; pp. 649.

Higgins, J.P.T., Green, S. ed. 2011. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0. The Cochrane Collaboration. [online]. Available from: <u>www.cochrane-handbook.org</u> [Accessed 23rd July 2013]

Huynh, C., Wong, I.C.K., Tomlin, S., Terry, D., Sinclair, A., Wilson, K., Jani, Y. 2013a. Medication discrepancies at transitions in pediatrics: a review of the literature. Pediatric Drugs, 15, pp. 203-215

Huynh, C., Jani, Y., Wong, I.C.K., Dewchand, B., Tomlin, S. 2013b. What is the current practice of medicines reconciliation in children nationally in the UK? International Journal of Pharmacy Practice, 21(1), pp. 62-65.

Institute for Healthcare Improvement. 2008. 5 Million Lives Campaign. Getting Started Kit: Prevent Adverse Drug Events (Medication Reconciliation) How-to Guide. Cambridge, MA. [online]. Available from www.ihi.org [Accessed 16th June 2011]

Jani, Y.H., Ghaleb, M.A., Marks, S.D., Cope, J., Barber, N., Wong, I.C.K. 2008. Electronic Prescribing Reduced Prescribing Errors in a Pediatric Renal Outpatient Clinic. The Journal of Pediatrics, 152, pp. 214-218.

Jani, Y.H., Barber, N., Wong, I.C.K. 2010. Paediatric dosing errors before and after electronic prescribing. Quality and Safety in Healthcare, 19, pp. 337-340.

Kaushal, R., Bates, D.W., Landrigan, C., McKenna, K.J., Clapp, M.D., Federico, F., Goldmann, D.A. 2001. Medication errors and adverse drug events in pediatric inpatients. The Journal of the American Medical Association, 285, pp. 2114-2120.

Kohn, L.T, Corrigan, J.M., Donaldson, M.S., eds. 2000. To Err Is Human: Building a Safer Health System. National Academy Press Washington DC [online]. Available from <u>http://www.nap.edu/catalog/9728.html</u> [Accessed 31st July 2013]

Kwan, Y., Fernandes, O.A., Nagge, J.J., Wong, G. Huh, J., Hurn, D., Bajcar, J. 2005. Implementation and a randomized controlled evaluation of pharmacist medication assessments in a surgical pre-admission clinic. Pharmacotherapy, 25, pp. 1462.

Kwan, Y., Fernandes, O.A., Nagge, J.J., Wong, G.G. Huh, J.H., Hurn, D.A., Bajcar, J.M. 2007. Pharmacist medication assessments in a surgical preadmission clinic. Archives of Internal Medicine, 167(10), pp. 1034-1040.

Lasak-Temme, L., Englert, L., Scarpace, S. 2008. Pharmacist initiated medication reconciliation in a children's hospital. The Journal of Pediatric Pharmacology and Therapeutics, 13(3), pp. 193-194.

Ling, J., Caligiuri, C., Galloway, L., Blydt-Hansen, T. 2009. Medication reconciliation: Towards a "Best Practice Medication Discharge Plan" in a Pediatric Hospital. Canadian Journal of Hospital Pharmacy, 62, pp. 345.

Marconi, G.P., Claudius, I. 2012. Impact of an emergency department pharmacy on medication omission and delay. Pediatric Emergency Care, 28(1), pp. 30-33.

McDonagh, J.E. 2005. Growing up and moving on: Transition from pediatric to adult care. Pediatric Transplantation, 9, pp. 364-372.

Miles, M.B., Huberman, A.M. ed. 1994. Qualitative Data Analysis. An Expanded Source book. 2nd ed. Sage publications.

Miller, M.R., Robinson, K.A., Lubomski, L.H., Rinke, M.L., Pronovost, P.J. 2007. Medication errors in paediatric care: a systematic review of epidemiology and an evaluation of evidence supporting reduction strategy recommendations. Quality and Safety in Healthcare, 16(2), pp. 116-26.

Miller, S.L., Miller, S., Balon, J., Helling, T.S. 2008. Medication reconciliation in a rural trauma population. Annals of Emergency Medicine, 52(5), pp. 483-491.

National Institute for Health and Clinical Excellence. National Patient Safety Agency. 2007. PSG001. Technical patient safety solutions for medicines reconciliation on admission of adults to hospital. [online]. Available from: <u>http://www.nice.org.uk/nicemedia/live/11897/38560/38560.pdf</u> [Accessed 24th July 2013]

National Patient Safety Agency.Root Cause Analysis investigationresources.[online].Availablefrom:http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/.[Accessed 31st May 2013]

National Prescribing Centre. Medicines reconciliation: a guide to implementation 2008. [online]. Available from: http://www.npc.nhs.uk/improving_safety/medicines_reconciliation/resources/r econciliation_guide.pdf [Accessed 7th November 2013]

Oxford University Press. 1996. The oxford compact English dictionary. Thompson, D. Ed., pp. 280.

Pharmaceutical Services Negotiating Committee. MUR frequently asked questions. [online]. Available from: <u>http://psnc.org.uk/services-commissioning/advanced-services/murs/mur-faqs/</u> [Accessed 7th November 2013]

Reeder, T.A, Mutnick, A. 2008 Pharmacist- versus physician-obtained medication histories. American Journal of Health-System Pharmacy, 65, pp. 857-860.

Ritchie, J., Spencer, L. 1994. Qualitative data analysis for applied policy research. In: Bryman, A., Burgess B., eds. Analysing Qualitative Data, London: Routledge, pp. 173 – 194.

Roger, G., Alper, E., Brunelle, D., Federico, F., Fenn, C.A., Leape, L.L, Kirle, L., Ridley, N., Clarridge, B.R., Bolcic-Jankovic, D., Griswold, P., Hanna, D., Annas, C.L. 2006. National Patient Safety Goals: Reconciling Medications at Admission: Safe Practice Recommendations and Implementation Strategies. Joint Commission Journal on Quality and Patient Safety, 32(1), pp. 37-50.

Rothschild, J.M., Churchill, W., Erickson, A., Munz, K., Schuur, J.D., Salzberg, C.A., Lewinski, D., Shane, R., Aazami, R., Patka, J., Jaggers, R., Steffenhagen, A., Rough, S., Bates, D.W. 2010. Medication Errors Recovered by Emergency Department Pharmacists. Annals of Emergency Medicine, 55(6), pp. 513-52.

Royal Pharmaceutical Society. Keeping patients safe when they transfer between care providers – getting the medicines right Final report. June 2012. [online]. Available from: <u>http://www.rpharms.com/current-campaigns-pdfs/rps-transfer-of-care-final-report.pdf</u> [accessed 7th November 2013].

Rozich, J.D., Resar, R.K. 2001. Medication Safety: One Organization's Approach to the Challenge. Journal of Clinical Outcomes Management, 8(10), pp. 27-34.

Shaw, K.L., Southwood ,T.R., McDonagh, J.E. 2004. User perspective of transitional care for adolescents with juvenile idiopathic arthritis. Rheumatology, 43, pp.770-778.

Stone, B.L., Boehme, S., Mundorff, M.B., Maloney, C.G., Srivastava, R. 2010. Hospital admission medication reconciliation in medically complex children: an observational study. Archives of Disease in Childhood, 95, pp. 250-56.

Strunk, L.B, Matson, A.W., Steinke, D. 2008. Impact of a pharmacist on medication reconciliation on patient admission to a Veterans affairs medical center. Hospital Pharmacy, 43, pp. 644-649.

Swinglehurst, D., Greenhalgh, T., Russell, J. Myall, M. 2011. Receptionist input to quality and safety in repeat prescribing in UK general practice: ethnographic case study. British Medical Journal, 343, pp. d6788.

Tam, V.C., Knowles, S.R., Cornish, P.L., Fine, N., Marchesano, R., Etchells, E.E. 2005. Frequency, type and clinical importance of medication history errors at admission: a systematic review. Canadian Medical Association Journal, 173(5), pp. 510-5.

Terry, D., Solanki, G., Sinclair, A., Marriot, J., Wilson, K. 2010. Clinical significance of medication reconciliation in Children admitted to a UK paediatric hospital. Pediatric Drugs, 12, pp. 331-337.

The Joint Commission Sentinel Event Alert. Issue 35. January 25, 2006.[online].Availablehttp://www.jointcommission.org/assets/1/18/SEA_35.PDF[Accessed 14thJanuary 2012]

Vira, T., Colquhoun, M., Etchells, E. 2006. Reconciliable differences: correcting medication errors at hospital admission and discharge. Quality and Safety in Health Care, 15, pp. 122-126.

Weingart, S.N., Cleary, A., Seger, A., Eng, T.K., Saadeh, M., Gross, A., Shulman, L.N. 2007 Medication reconciliation in ambulatory oncology. Joint Commission journal on quality and patient safety, 33(12), pp. 750-757.

White, C.M., Schoettker, P.J., Conway, P.H., Geiser, M., Olivea, J., Pruett, R., Kotagal, U.R. 2011. Utilising improvement science methods to optimise medication reconciliation. British Medical Journal: Quality and Safety, 20(4), pp372-380

WHO Collaborating Centre for Patient Safety Solutions. May 2007. Assuring Medication Accuracy at Transitions in Care. Patient Safety Solutions volume 1, solution 6. [online]. Available from: http://www.who.int/patientsafety/solutions/patientsafety/Solutions/patientsafety/PS-Solution6.pdf [accessed 5th August 2013]

Wilson, H., Barber, N. Review of NHS Pharmaceutical Care of Patients in the Community in Scotland. August 2013. Available from: <u>http://www.scotland.gov.uk/Resource/0043/00430209.pdf</u> [accessed 7th November 2013]

World Health Organization. 2008. Summary of the evidence on patient safety: Implications for research. [Online]. Available from: - <u>http://whqlibdoc.who.int/publications/2008/9789241596541_eng.pdf</u> [Accessed 5th August 2013].

Wong, I., Basra, N., Yeung, V., Cope, J. 2006 Supply problems of unlicensed and off-label medicines after discharge. Archives of diseases in childhood, 91, pp. 686-688.

Wong, I.C., Ghaleb, M.A., Franklin, B.D., Barber, N. 2004. Incidence and nature of dosing errors in paediatric medications. A systematic review. Drug Safety, 27, pp. 661-670.

Wong, I., Wong, L., Cranswick, N. 2009a. Minimising medication errors in children. Archives of Disease in Childhood, 94, pp. 161–164.

Wong, J.D., Bajcar, J.M., Wong, G.G., Alibhai, S.M., Huh, J.H., Cesta, A., Pond, G.R., Fernandes, O.A. 2008. Medication reconciliation at hospital discharge: Evaluating discrepancies. Annals of Pharmacotherapy, 42(10), pp. 1373-1379.

Appendices

Appendix A – Pre-assessment study form used in admissions study (Chapter 2)

CONFIDENTIAL - MEDICATION-RECONCILIATION MULTISITE STUDY

PATIENT'S STUDY ID

NPPG-MR STUDY INSTRUMENT #v2

BCH / EVELINA / LEEDS / STAFFS

DATE & START TIME			
PATIENT'S FULL NAME			
HOSPITAL NUMBER			
WARD / UNIT			
DATE OF ADMISSION			
Predicted DISCHARGE DATE			
SPECIALTY			
DOB			
WEIGHT (kg)			
PRESENTING COMPLAINT, CHRONIC ILLNESSES			
SOURCE OF ADMISSION (If not primary-care do NOT complete MR)			
Does patient have chronic condition usually requiring LTMs?	YES /	NO	
Does caregiver confirm taking LTMs?	YES /	NO	
For full MR	YES /	NO	
COMPLETED BY?			
TOTAL TIME TO COMPLETE THIS PAGE (Mins)			
COMMENTS			

PRE-STUDY ASSESSMENT SHEET

Source: - Form developed and adapted from Terry et al 2010.

Appendix B – Data collection form used for Admissions study (Chapter 2)

CONFIDENTIAL - MEDICATION-RECONCILIATION MULTISITE STUDY

	STUDY ID
18/2	BCH / EVELINA / LEEDS / STAFFS
INSTRUMENT	PATIENT DETAILS
	Attach PRE-STUDY ASSESSMENT SHEET HERE
MR STUDY	
M-Ddd	
₽	

CAREGIVER INTERVIEW (Tech or Pharm)

	DATE			
	DAY & START TIME			
	INTERVIEWEE			
	INTERVIEWER			
	NO. OF ATTEMPTS TO CONDUCT INTERVIEW			
	DRUG ALLERGIES?			
	PODS?	YES / NO		
nes	GP DETAILS (INC. TELEPHONE)			
Identify what the patient is actually being given. Include OTC medicines	CP DETAILS			
clude O	TOTAL TIME TO COMPLETE THIS PAGE (Mins)			
/en. In	INFORM CAREGIVER WE WILL CONTACT GP	(<u>Tick when done)</u>		
nggi				
ly bei	DRUG	DOSE, FORM ROUTE	SOURCE	BNF CHAPTER
actual			Caregiver	
ntis			Caregiver	
patie			Caregiver	
at the			Caregiver	
ify wt			Caregiver	
Ident			Caregiver	
	Comments			

PRE-ADMISSION (PRESCRIBED) MEDICATION (PAMs) - GP ONLY

DATE				
DAY & START TIME				
OBTAINED BY				
SOURCE (GP or Receptio	nist)			
CONTACT TELEPHONE				
NO. OF ATTEMPTS TO CONTACT				
Formal request required	?	YES / NO		
TOTAL TIME TO COMPLE THIS PAGE (Mins)	TE			
DRUG		DOSE, FORM ROUTE	SOURCE	BNF CHAPTER
			GP	

Comments

PRE-ADMISSION (PRESCRIBED) MEDICATION (PAMs) - GP ONLY

DATE				
DAY & START TIME				
OBTAINED BY				
SOURCE (GP or Receptio	nist)			
CONTACT TELEPHONE				
NO. OF ATTEMPTS TO CONTACT				
Formal request required	?	YES / NO		
TOTAL TIME TO COMPLE THIS PAGE (Mins)	TE			
DRUG		DOSE, FORM ROUTE	SOURCE	BNF CHAPTER
			GP	

Comments

-

ADMISSION MEDICATION ORDERS - DRUG CHART (LTMs only)

DATE	
DAY & START TIME	
OBTAINED BY	
SOURCE	Drug chart / eRxs / Medical notes
NO. OF ATTEMPTS TO OBTAIN	
REFER DISPARITIES TO?	
TOTAL TIME TO COMPLETE THIS PAGE (Mins)	

DRUG	DOSE, FORM ROUTE	If disparity is change intentional?	BNF CHAPTER
		Yes / No	

Comments

PATIENT'S OWN DRUGS - PODs

DATE	
DAY & START TIME	
OBTAINED BY	
NO. OF ATTEMPTS TO OBTAIN	
TOTAL TIME TO COMPLETE THIS PAGE (Mins)	

DRUG	DOSE, FORM ROUTE	SOURCE	BNF CHAPTER
		POD	

Comments

PHARMACIST RECOMMENDED THERAPY

DATE	
DAY & START TIME	
DETERMINED BY	
TOTAL TIME TO COMPLETE THIS PAGE (Mins)	

DRUG	DOSE, FORM ROUTE	BNF CHAPTER

INTERVENTIONS AND OUTCOMES

[

	
Comments	

Instructions:

Assign the next unique number for each new patient

Complete details in all boxes.

Remember to record how long each page of information takes to complete.

Sensitivity and specificity details will be determined once the validated CPM is identified

The caregivers do not have to sign for consent – take verbal consent and record that you have obtained it.

Sensitivity = nT+ves / (nT+ves + nF-ves)

Specificity = nT-ves / (nT-ves + nF+ves)

Disparity levels will be determined by an expert clinical panel at the end of data collection

Appendix C – Pharmacist led medication reconciliation in children – pathway intervention (Admission)

Last updated – Friday 10th February 2012

Choose appropriate graded pathway according to availability. The pharmacist undertaking the medication reconciliation should seek to use the pathways in the following order: A before B, B before C. The three pathways will all lead to a best procedure for carrying out the medication reconciliation depending upon circumstances.

Medication reconciliation should be carried out on all children on long term.

Choices of pathway: -

Path A. Parent/carer interview start point

Path B. POD data collection start point (only choose this when the parent/carer is unavailable). Please do not state unlabelled PODs as a source at this start point until confirmation with parents.

Path C. Notes from previous care provider start point (only choose when the parent/carer is unavailable and the patient has no PODs)

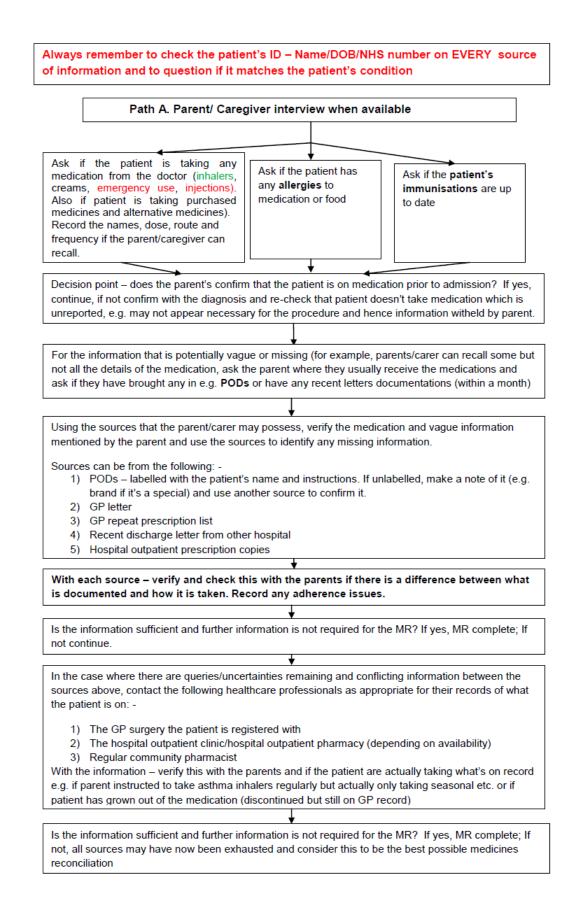
Order of preference of pathway to take: - (most preferred) A > B > C (least preferred)

Important points to note

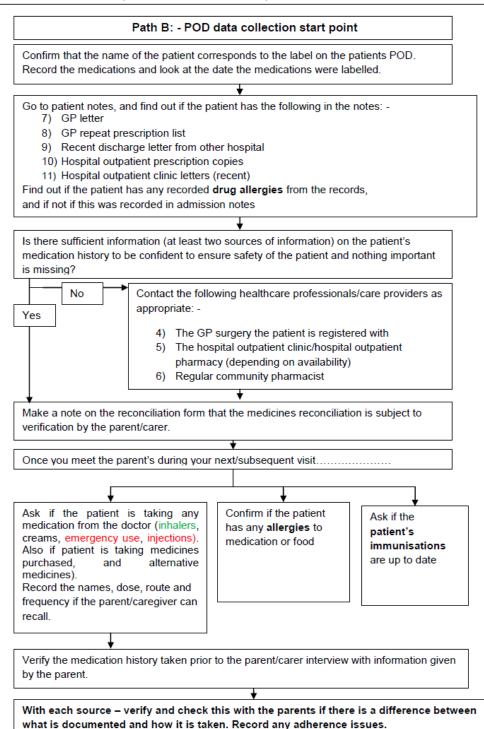
It is suggested that a minimum of **two sources** of information should be used to reconcile the medication and there is no restriction to how many sources to use. Please do not hesitate to use more than two sources of information and as many should be used as required to obtain the full medication history to the best possible accuracy.

Clarification with a GP source is ideal. However, direct GP contact (via phone or request for written information) should only be necessary when if there is a reasonable degree of clinical doubt with the documented history.

Summarised medication reconciliation pathway diagram (on next page)



Always remember to check the patient's ID – Name/DOB/NHS number on EVERY source of information and to question if it matches the patient's condition



Always remember to check the patient's ID – Name/DOB/NHS number on every source of information and to question if it matches the patient's condition

Path C: - Notes from previous care provider start point

Go to patient notes, and find out if the patient has the following in the notes: -1) GP letter

- 2) GP repeat prescription list
- 3) Recent discharge letter from other hospital
- 4) Hospital outpatient prescription copies
- 5) Hospital outpatient clinic letters (recent)

Find out if the patient has any recorded **drug allergies** from the records, and if not if this was recorded in admission notes

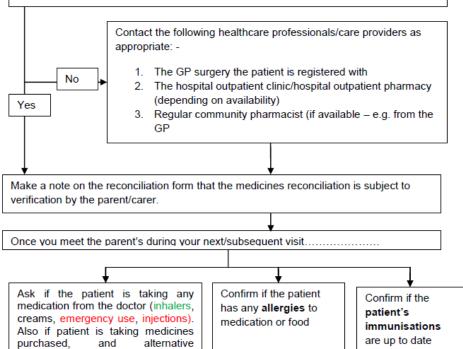
If not if this was recorded in admission note

medicines).

recall.

Record the names, dose, route and frequency if the parent/caregiver can

Is there sufficient information on the patient's medication history to be confident to ensure safety of the patient and nothing important is missing?



Verify the medication history taken prior to the parent/carer interview with information given by the parent.

With each source – verify and check this with the parents if there is a difference between what is documented and how it is taken. Record any adherence issues.

Appendix D – Pharmacist led medication reconciliation in children intervention – Data collection form

Front of data collection sheet							Patient	t ID number:		
	Medicir	nes recor	ciliation for	children at	t hospital	admission	Drug His	story taking – Colle	ction form	
Hospital Number Patient Surname Patient First name	me :-							Allergy status (I	Allergy status (Do not leave blank): -	
Gender (Male/Female): -				Consultant :-				Vaccination status up to date (circle one)? Yes/No State pending vaccines and date due: -		
Weight (kg): Height (cm): Body Surface Area (m ²): Dat						Date of admission: - Ac			:	
Regular Community Ph Pathway used Please ci	armacy Name ircle : (A / B /	<mark>e, Telepho</mark> C) Date	ne and Fax: - Medication H	listory taken	n:				Form of	
A. Medication name and dosage form	B. Dose	C. Route	D. Frequency	E. Sources and order	s used	F. Last taken patient (DD/M	by M/YY)	G. Pharmacist Recommend (Stop/Continue/ Hold/change/other)	H. Notes (Please state in detail which information was obtained from each source)	
Medication history tak Signature Contact/Bleep number		Pharma	acist/Pharmac	(fu cy technician	ll name) n/Pre-reg	Signature		mmendation taken by Phar	:(full name) macist 	

Back of data collection sheet	Patient ID number:					
	in the formul					
Comments box (Additional information that could not be included in	in the form)					
A guide on filling in the date collection form						

A guide on filling in the data collection form

For the purpose of ensuring consistency of data please fill in the columns of the data collection form as follows: -

Patient ID – Please assign an ID number to the patient. For Birmingham start assign numbers from 1 – 30, Evelina 31 – 60, Leeds 61 – 90, North Staffordshire 91 – 120.

Sources used (please tick and circle relevant): - \Box Notes – GP Letter (GP-N); \Box Notes repeat slip (GP-R); \Box A&E note (A&E); \Box Previous hospital drug chart (PHC); \Box Previous hospital discharge letter (PHTTA); \Box Parents/Patient or Carer – From a list/Interview information (PPC); \Box Patient's Own Drug (POD); \Box GP – via telephone (GPT); \Box GP – Fax (GPF); GP summary (GP-S); \Box Community pharmacist (CP); \Box Summary care record (SCR); \Box Other –

Guidance on how to fill the boxes

- A. Medication name and dosage form Please state the generic and brand name of the medication and also the strength and formulation. For Liquids please state the units per volume e.g. 100mg/5ml. For tablets please state the strength e.g. 500 units or 50mg etc.
- B. Dose please state the dose to be given to the patient e.g. 25mg. In the case of liquid please state the dose in both volume and strength e.g. 5ml (20mg).
- C. Please state the Route: e.g. oral, buccal, im injection, via gastronomy tube PEG etc
- D. Please state the Frequency e.g. once daily, once a week, PRN (in terms of inhaler please state how many puffs when PRN)
- E. Sources used and order This may seem like a repeat of the above "sources used and order of access" but you may have reconciled each medication using a combination of different sources. For example, overall you used 3 sources, 1. Parent, 2 PODs and 3. Specialist allergy clinic. For a drug e.g. omeprazole you used 1 and 2 to reconcile but for Epipen you used 1 and 3 to reconcile.
- F. State when the last dose was taken by the patient
- **G.** Pharmacist recommended therapy. State stop, continue, hold or change. For change, write down the suggested dose, strength of preparation route directions and reason for change (use notes if you run out of space)
- H. In the notes (for sources where you obtained different information from each source) please specify which information was obtained from which source and the reason for using an additional source to reconcile the medication.

Appendix E – Medication reconciliation upon hospital admission multisite admission study – Focus group moderator's question guide Method/Question guide

Introduction

Good morning everyone. Thank you for attending the focus group session. During the course of this focus group session we will be discussing and finding out your views on the medication reconciliation pathway and form that was piloted across children's wards across the four sites.

Focus group ground rules

Before we start the focus group just some information and ground rules

I will be recording the focus group, however, in any transcripts and reports, all your details will be kept anonymous.

Opening questions (10 minutes)

Before we start on the key questions, I would like to ask you all to discuss

- What would you define as admission medication reconciliation in children and what this means to your practice?
- How do you normally prioritise your time and identify patients who would require more than a Nil regular medications medication history (e.g. on long term therapy and subsequent reconciliation?
- 3) How you would usually reconcile medicines and what would you usually use?

4) How often do you meet complex paediatric patients who have been on long term therapy prior to admission and before you saw the intervention – did you have your own personal procedure written or non-written of how to go about reconciling medications and drawing information?

Ok now that we have gathered the group member's views in terms of the definition and each other's own process lets discuss the medication reconciliation intervention pathway and form that was piloted across the four sites.

Key Question 1 (15 minutes) Discussion on the medication reconciliation pathway

Now I would like to discuss your views about using the guided pathways in the intervention. What was different and similar to what you would normally do to reconcile the medication history in practice?

Key Question 2 (15 minutes) Discussion on the medication reconciliation data collection form

Now that we have discussed the pathway, for the next session, let's discuss the data collection form. How did you find using the MR form to record the information? Were there any practical issues? What do you think we should include and what should be exclude?

Tea break

Key Question 3 (15 minutes)

I would now like to discuss what are your views and opinion on having a paediatric specific tool in medication reconciliation?

What are the differences in meds rec in children?

Key Question 4 (15 minutes) Now that we have talked about the pathway, form and algorithm, lets discuss your views on who should carry out the medication reconciliation intervention?

Also in your opinion do you think parts of this process can be delegated to trained Pre-Reg pharmacy students and technicians? How much responsibility in your opinion and view would you delegate to? Ending questions (10 minutes)

That is very useful; we now need to draw the focus group to a close. Before we finish I would like to ask you to raise any other issues in general regarding the paediatric medication reconciliation, which we may not have discussed? We have 10 minutes left.

Once again I would like to thank you for attending the focus group. This has been very helpful and I hope that each one of you have also learnt something or will be able to take home.

10:30am – 1pm

Appendix F – 14 day post hospital discharge interview of GP surgery staff schedule: - Questions for GP Practice manager /administrator

"Good afternoon, I'm calling from the Evelina Children's hospital pharmacy, at the moment we are carrying out a service evaluation on our discharge process in terms of the communication of medication information on our discharge letters.

- We would like to ask if you have received (patient name)'s discharge summary, prescription record?
- Was the date it was received recorded, what date was it recorded as?
 When did you receive it?
- What format did you receive it in? Email only; Paper Copy; email and paper copy
- What normally happens when you receive the letter? [Do you date stamp or note it in the GP record?]
- 5. When does the GP normally see the letter?
- 6. Does the GP aim to review this letter within a certain timeframe of receipt?

- 7. If you have seen that the medications have changed after hospitalization, how will the GP find out about this? Is there a flag or alert on the computer system to indicate this?
- 8. When the GP makes changes to the medicines based on the discharge letter, do they update the computer system or does somebody do it on their behalf?
- 9. If the discharge patient has new medications who adds them onto the computer system? And if the medications are to be discontinued, who removes them? (We understand that it would be under the GP's directions in terms of initiating or discontinuing the medications but we understand that the practice manager may deal with the administrative side and this is why we are asking)
- 10. As some of the medications we discharge the patient on are sometimes made as a special/unlicensed and may not be on your computer system – how would you document this on your computer system? Do you free type it or enter it on another part of the computer system?
- 11. When there are a lot of changes in a patient's therapy post hospital discharge, would you do anything different?

- 12. If you had any queries with medicines on discharge letters, does the surgery have a procedure with dealing with this?
- 13. Following from the previous question would you/have you ever needed to contact the patient/carer or hospital get contacted for clarification?
- 14. Once this issue is resolved, is this change fully documented in the clinical notes for the patient?
- 15. In terms of your process of reviewing changes in medication after discharge – does the GP consider the review complete when they go over the discharge letter from the hospital or would the GP only consider that it is complete when they go over the discharge letter and see the patient in an appointment post discharge?
- 16. Thank you for your time.

Appendix G – Data capture form for GP surgery reception staff interview

ID Number: -

Question	Question	Response
1	TTA received	Yes/No
2	Date recorded?	State Date DD/MM/YYYY
3	Paper/Email?	Paper □ Email □
4	Date stamp or note in record?	Date Stamp
5	Stage GP see's letter	Note in Record Free text
6	Timeframe of addressing TTA?	Free text
7	Medication changes and alert, flag system?	Free text
8	Updates entered on system by?	(Name the staff e.g. GP, Receptionist, Practice manager)
9	Adding and removing drugs – who does it on the computer?	Free text
10	How do they deal with unlicensed drugs?	Free text
11	Action taken to deal with major change?	
12	GP procedure for dealing with queries on TTAs?	Free text
13	Who is contacted (Following question 10)?	Patient/Parent
		Hospital □ Other □
14	Full documentation of change?	Yes 🗆
15	Review procedure complete	No TTA review TTA and Patient review

Appendix H – Initial thematic framework for the telephone follow up and interview of GP surgery staff 14 days post hospital discharge (non exhaustive and based on initial familiarization with data)

Main code	Sub codes (or nVIVO nodes)
5 Stage of which the GP see's discharge letter	5.1 Straight away5.2 Seen via email5.3 When paper discharge letter is scanned
6 Timeframe of addressing TTA?	6.1 Straight away 6.2 Within a week
7 Medication changes and alert, flag system?	7.1 No system
8 Updates entered on system by?	8.1 GP directly8.2 Practice manager8.3 Administrator
9 Adding and removing drugs – who does it on the computer?	9.1 GP 9.2. Practice manager
10 Surgery procedure - dealing with unlicensed drugs	10.1 Handwritten prescription 10.2 Referral to medicines management 10.3 Surgery does not deal with unlicensed
11 Action taken to deal with major change	11.1 GP 11.2 Administrator under instruction of GP
12 GP procedure for dealing with queries on TTAs	12.1 Contacts parent 12.2 Contacts hospital
14 Documentation of changes to a patient's medication post discharge (record)	
15 Post discharge review procedure complete	15.1 After review with patient in person 15.2 After discharge letter is reviewed

Appendix I – Finalized thematic framework for the telephone follow up and interview of GP surgery staff 14 days post hospital discharge (non exhaustive and based on initial familiarization with data)

Main code	Sub codes (or nVIVO nodes)
5 Stage at which the GP see's discharge letter	 5.1 Seen by the GP first upon receipt 5.2 Seen via email from hospital 5.2b Received by email from hospital. Printed out, scanned and passed onto relevant GP 5.2c Received by email printed then print out seen by GP 5.3 When paper discharge letter is scanned 5.4 Same day of receipt 5.5 Unsure (practice manager or administrator) 5.6 When the IT technician sends it to the GP electronically 5.7 When it is put in the GPs in-tray 5.8 Varies – when the patient brings the discharge summary in or when the letter is received through the post
6 Timeframe of addressing TTA?	 6.1 Day of receipt or same day 6.2 Within a week 6.3 Unknown 6.4 When it appears in GPs inbox 6.5 Prioritised depending on if there is a change or no change 6.6 Within 48 hours of receipt 6.7 A few days
7 Medication changes and alert, flag system?	 7.1 No system 7.2 Unsure 7.3 Indication of change 7.4 Indication of no action required 7.5 Indication of no change 7.6 Added medication 7.7 GP flags changes. Reception to amend on system 7.8 Number of medication added recorded 7.9 Changes flagged by receptionist and scanned 7.10 No action required or recorded 7.11 Basic changes for reception to add after GP seen discharge letter 7.12 GP flags changes 7.13 Receptionist makes a note on the patient's record for the GP 7.14 Prescription co-ordinator flags up changes

Main code	Sub codes (or nVIVO nodes)
	 7.15 Duty doctor makes immediate or urgent changes 7.16 GP flags for practice manager 7.17 Duty doctor flags major changes to GP
8 Updates entered on system by?	 8.1 GP directly 8.2 Practice manager 8.3 Administrator 8.4 Administrator and or GP 8.5 Receptionist 8.6 Clerks 8.7 Prescription clerk or GP 8.8 GP or prescription co-ordinator 8.9 Prescription clerk or duty doctor 8.10 GP or receptionist 8.11 Dispensers 8.12 Duty doctor 8.13 GP or duty doctor
9 Adding and removing drugs – who does it on the computer?	 9.1 GP 9.2 Practice manager 9.3 Administrator or GP 9.4 GP presumed 9.5 Administrator 9.6 Reception staff 9.7 Prescription team 9.8 Clerk 9.9 GP or Clerk 9.10 Prescription co-ordinator – double checked by GP 9.11 Clerk or duty doctor 9.12 Dispensers 9.13 Duty doctor 9.14 GP or duty doctor
10 Surgery procedure - dealing with unlicensed drugs	 10.1 Handwritten prescription 10.2 Surgery does not deal with unlicensed 10.3 FP10 – would be on the system 10.4 Dealt with by GP surgery based pharmacist 10.5 Dealt with by prescription team 10.6 GP adds to system 10.7 Contact PCT 10.8 Sends patient back to hospital for further supply 10.9 Contact hospital 10.10 Respondent (manager or receptionist) didn't know

Main code	Sub codes (or nVIVO nodes)
11 Action taken to deal with major change	 11.1 GP 11.2 Administrator under instruction of GP 11.3 Handwritten 11.4 Patient referred to GP practice based pharmacist 11.5 Dealt with by prescription team 11.6 Receptionist refers change to GP 11.7 Receptionist will be asked by GP to contact parent 11.8 GP requests to see patient 11.9 GP contacts consultant 11.10 Dealt with upon request of medication 11.11 Contact hospital 11.12 Reception or administrator contacts patient then informs GP 11.13 Patients contacted 11.14 Receptionist asked by GP to contact hospital 11.15 Consultant contacted
12 GP procedure for dealing with queries on TTAs	 12.1 Contacts parent 12.2 Contacts hospital 12.3 Varies 12.4 Refers to practice based pharmacist
14 Documentation of changes to a patient's medication post discharge (record)	14.1 Drugs added to repeat14.2 Recorded on computer system14.3 Patient's notes14.4 Patient notes and computer system
15 Post discharge review procedure complete	 15.1 After review with patient in person 15.2 After discharge letter is reviewed 15.3 Patient was not reviewed nor contacted when TTA reviewed 15.4 Both TTA and patient used to review 15.5 Not known

Appendix J – Sample of Parent/Patient information leaflets

Information about the research - For parents/carer

Medicines Reconciliation Research in Young patients Post Discharge (MERRY-PD)

An invitation

We would like to invite you and your child to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 5 minutes.

Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Part 1 – this tells you the purpose of this study and what will happen to you if you take part

What is the purpose of our study?

Medication related problems can occur when patients are admitted into and discharged from hospital. There is no specific information or studies on how this affects children. Our study aims to fill this knowledge gap by conducting follow up interviews with the parents/carers of children who are on long term medication, to find out how they are getting on with the medicines. We want to identify the causes of any problems related to medication that may occur when children on long term medicines leave hospital back for home.

What does the term "medicines reconciliation" in the title mean?

Medicines reconciliation is "the process of creating the most accurate list possible of all medications a patient is taking including drug name, dosage, frequency, and route and comparing that list against the doctors' admission, transfer, and/or discharge medication orders, with the goal of providing correct medications to the patient at all transition points."

Why have you and your child been invited?

Your child and you have been invited to participate in this research project because your child has been discharged on medicines which will be continued by your GP.

Do you and your child have to take part?

It is up to you to decide if your child and you would like to be part of this follow up study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. We will also be seeking agreement (assent) from your child. You are free to decide to withdraw from the study at any time and we will not ask for a reason why. This would not affect the standard of care you receive.

What will happen to me and my child if I take part?

If you decide to take part, we will arrange to visit you, or if you live further than 1 hour from the hospital, telephone you, 3 weeks after your child has gone home from hospital, to find out how you are getting on with your child's medication.

We will ask you some questions about your child's current long term medication to find out:

- what the current list of your child's long term medications is
- if your child's current medication list differs from how it was upon discharge.

We will also be contacting your child's GP and community pharmacist, about your child's medication.

Version 10.4 Last updated 30/11/2011

Information about the research – For parents/carer (Part 2)

How much time would this involve?

The whole process of discussing your child's medicines by telephone or on a home visit would take approximately 20 minutes.

We would like the follow up visit or telephone call to be after you have requested further supplies for your child's medication from your GP. If you have not yet requested further supplies for your child's medication from your GP by the date arranged, we will re-arrange the follow up for a time after you have visited your GP for further medication supplies. This means that we may need to visit or telephone you on two occasions during the study.

What will my child or I need to do?

You will need to spend some time talking about your child's medicines to the research pharmacist either over the telephone or in person. Your child will not need to do anything different.

The flow chart at the end of this information sheet provides a summary of what taking part in the study will involve.

What are the risks and the possible benefits of taking part?

Taking part in the study will give you the opportunity to discuss your child's medicines with a qualified pharmacist.

The information that we get from the study will help improve our understanding of any issues that may occur with obtaining further medication supply following your child's hospital discharge.

We also plan to use the results to help improve the transfer and interpretation of medication related information between the hospital, GP and community pharmacy.

What happens if there is a problem?

If there is a problem or if you have a complaint about the way you have been dealt with during the study, this will be addressed - see part 2.

Will my participation in the study and my child's involvement be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Please see part 2 for further details.

If the information in Part 1 has interested you and your child, and both are considering participating in the study, please read the additional information in Part 2 before making any decision

Part 2 – This part will provide more details about the conduct of the study

What will happen if I don't want to carry on with the study?

You can choose to withdraw at any point of the study. This will not affect your child's current treatment.

What if there is a problem?

Should a problem arise, the research pharmacist will refer and signpost to the most appropriate authority depending on the nature of the problem.

Will our participation (parent/carer's and child's) in the study be kept confidential?

Yes, your participation is kept confidential.

The research pharmacist has a contract with the hospital trust and will follow and adhere to the confidentiality procedures of the hospital and will have a duty of confidentiality to you as the research participant. We will do our best to meet this duty.

Involvement of the General Practitioner/Family doctor

We will send the GP a letter of notification of the study. During the follow up, if we find any differences between the list you provide in comparison to the medicines prescribed after discharge, we will

Version 10.4 Last updated 30/11/2011

Information about the research - For parents/carer (Part 2)

contact the GP to discuss this further. Only information relating to your child's medication will be exchanged for this for clarification.

What will happen to the results of the research study?

Results of the research study will be written up as a report for the funding body of the study. Please note that your child and you will not be identified in any report or publication of results. If you are interested and would like to see the results, a copy of the final report will be made available on request.

Who is funding the research study?

The cost of running this study has been made possible from funding provided by the Pharmacy Practice Research Trust an independent research charity, with a broad objective to promote and develop the field of pharmacy practice research. Registered Charity: 1076457.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your child and your interests. This study has been reviewed and given favourable opinion by Riverside Research Ethics Committee.

If your child and you are happy to participate in the study we will enclose the following: -

- Patient information sheets for parents Part 1 and Part 2 (Version 10.2 Last updated 26/11/2011)
- Patient information sheets for your child (this will be age appropriate), if your child is under five, please read the leaflet and explain this to your child
- Consent form for you to sign
- Assent form for your child to sign or for you to sign on their behalf

Complaints

Please contact the research team should you want to make a complaint regarding the study.

Mr Stephen Tomlin, Chief investigator (Evelina Pharmacy)

Email: Phone: -

Dr Yogini Jani, Principal investigator (UCLH Pharmacy) Email: Phone: -

Mr Chi Huynh, Research Pharmacist

Email: Phone:

If you remain unhappy and wish to make a formal complaint, please contact the Patient Advise and Liaison Service using the information given below: -

Site: -

Email: -

Phone: -

For further information: - Please contact your ward pharmacist, or

Mr Chi Huynh, Research Pharmacist.

Telephone

Email:

Version 10.4 Last updated 30/11/2011

Page 3

Information about the research - For parents/carer (Part 2)

Flow chart of the study

Your child, who is on long term medication, is admitted to hospital. Our team pharmacist will approach you and introduce you to the study. You and your child will have the length of the stay to decide whether or not to consent (parent) / assent or agree (child) At discharge - if you have consented and your child has agreed to take part, the research team will obtain your contact details for follow up purposes. They will also record the medicines that your child is on at discharge. At this point we would also book and arrange a suitable and convenient time for a follow up visit or a phone call 21 days after your child is discharged. If you have given consent and chosen to If you have given consent and chosen to be followed up 21 days after your child be followed up 21 days after your child has left hospital via telephone has left hospital via home visit At the pre-arranged time 21 days later The research pharmacist will ask you if The research pharmacist will visit your you have seen your GP for further home. If you have not seen the GP for supplies of medicines. If you haven't, further supplies of your child's the research pharmacist will arrange medicines, an alternate date to visit will another time to call be arranged. We will compare the medicines that your child would be taking according to the information you provide (either in person or on the phone) with the hospital discharge medicines. If a difference occurs between the discharge medicines that were originally prescribed and what your child was on at the time of interview - we will contact the GP and the community pharmacist as appropriate.

Version 10.4 Last updated 30/11/2011

Medicines Reconciliation Research in Young patients Post Discharge (MERRY-PD)

An invitation

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 5 minutes.

Talk to others about the study if you wish. Ask us if there is anything that is not clear.

Part 1 this tells you the purpose of this study and what will happen to you if you take part.

What is the purpose of our study?

Medication related problems occur when patients are admitted into and discharged from hospital. There is no specific information or studies on how this affects children. Our study aims to fill this gap of knowledge by conducting follow up interviews of the parents/carers of children who are on long term medication, to find out how they are getting on with the medicines. We want to identify the causes of problems related to medication that may occur when children on long term medicines leave hospital back for home.

What does the term "Medicines reconciliation" in the title mean?

Medicines reconciliation is "the process of creating the most accurate list possible of all medications a patient is taking including drug name, dosage, frequency, and route and comparing that list against the doctors' admission, transfer, and/or discharge medication orders, with the goal of providing correct medications to the patient at all transition points."

Why have you been invited?

You have been invited to participate in this research project because you have been discharged on medicines which will be continued by your GP.

Do you have to take part?

It is up to you to decide if you would like to be part of this follow up study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to decide to withdraw from the study at any time, and we will not ask for a reason why. This would not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part, we will arrange to visit you, or if you live further than 1 hour from the hospital, telephone you three weeks after you leave hospital to find out how you are getting on with your medication. We will ask you some questions about your current long term medications to find out:

- A list of your current long term medications
- If your current medication list differs from how it was upon discharge.

We will also be contacting your GP and Community pharmacist, about your medication.

How much time would this involve?

The whole process of discussing your medicines by telephone or on a home visit would take approximately 20 minutes.

We would like the follow up visit or telephone call to be after you have requested further supplies of your medication from your GP. If you have not yet requested further supplies from your GP by the date arranged, we will re-arrange the follow up for a time after you have visited your GP for further medication supplies. This means that we may need to visit or telephone you on two occasions during the study.

What will I need to do?

You will need to spend some time talking about your medicines to the research pharmacist over the telephone or in person.

The flow chart at the end of this information sheet provides a summary of what taking part in the study will involve.

What are the risks and the possible benefits of taking part?

Taking part in the study will give you the opportunity to discuss your child's medicines with a qualified pharmacist.

The information that we get from the study will help improve our understanding of any issues that may occur with obtaining further medication supply following your hospital discharge.

We also plan to use the results to help improve the transfer and interpretation of medication related information between the hospital, GP and community pharmacy.

What happens if there is a problem?

If there is a problem or if you have a complaint about the way you have been dealt with during the study, this will be addressed – see part 2.

Will my participation and involvement in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Please see part 2 for further details.

If the information in Part 1 has interested you and you are considering participating in the study, please read the additional information in Part 2 before making any decision.

Part 2 – This part will provide more details about the conduct of the study

What will happen if I don't want to carry on with the study?

You can choose to withdraw at any point of the study. This will not affect your current treatment.

What if there is a problem?

Should a problem arise, the research team will refer and signpost to the most appropriate authority depending on the nature of the problem.

Will my participation the study be kept confidential?

Yes, your participation is kept confidential.

The research pharmacist has a contract with the hospital trust and will follow and adhere to the confidentiality procedures of the hospital and will have a duty of confidentiality to you as the research participant. We will do our best to meet this duty.

Involvement of the General Practitioner/Family doctor

We will be sending your GP a letter of notification. During the follow up, if we find a difference between what the doctors have prescribed to you in comparison to the medicines prescribed after discharge, we will contact your GP to discuss this further. Only information relating to your medication will be exchanged for this for clarification.

What will happen to the results of the research study?

Results of the research study will be written up as a report for the funding body of the study. Please note that you will not be identified in any report or publication of results. If you are interested and would like to find out the results of the study, a copy of the final report will be made available on request.

Who is funding the research study?

The cost of running this study has been made possible from funding provided by the Pharmacy Practice Research Trust an independent research charity, with a broad objective to promote and develop the field of pharmacy practice research. Registered Charity: 1076457.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your child and your interests. This study has been reviewed and given favourable opinion by Riverside Research Ethics Committee.

If you are happy to participate in the study we will enclose the following: -

Patient information sheets for young persons aged 16-18 years
 Part 1 and Part 2 (Version 10.2 Last updated 26/11/2011)

Consent form for you to sign

Complaints

Please contact the research team should you want to make a complaint regarding the study.

Chief investigator (Evelina Pharmacy): -

Mr Stephen Tomlin,
Email:
Phone:

Principal investigator (UCLH pharmacy): -

Dr Yogini Jani	
Email:	
Phone: -	

Research Pharmacist: -

Mr Chi Huynh,	
Email:	
Phone:	

If you remain unhappy and wish to make a formal complaint, please contact the Patient Advise and Liaison Service using the information given below: -

PALS at

Site: -Email: -Phone: -

For further information: - Please contact Mr Chi Huynh, Research

Pharmacist. Telephone . Email:

Flow chart of the study

At the time of your hospital admission: - Our team pharmacist will approach you and introduce you to the study. You will have the length of the stay to decide whether or not to consent. At discharge - if you have consented and agreed to take part, the research team will obtain your contact details for follow up purposes. They will also record the medicines that you are on at discharge. At this point we will also book and arrange a suitable and convenient time for a follow up visit or a phone call 21 days after you are discharged If you have given consent and chosen to If you have given consent and chosen to be followed up 21 days after you have be followed up 21 days after you have left hospital via telephone left hospital via home visit At the pre-arranged time 21 days later The research pharmacist will ask you if The research pharmacist will visit your you have seen your GP for further home. If you have not seen the GP for supplies of medicines. If you haven't, further supplies medicines, an alternate the research pharmacist will arrange date to visit will be arranged. another time to call We will compare the medicines that you would be taking according to the information you provide (either in person or on the phone) with the hospital discharge medicines. If a difference occurs between the discharge medicines that were originally prescribed and what you would be on at the time of interview - we will contact the GP and the community pharmacist as appropriate.

Version 10.4 Last updated 30/11/2011

Medicines Reconciliation Research in Young patients Post Discharge (MERRY-PD)

We would like to invite your parent and you to take part

We are looking to identify the causes of problems with medicines that happen when children and young people leave hospital and would like to invite your parent/carer to take part in this study. As part of the study, we will be in contact with your parents three weeks after you leave hospital to follow up and find out how you are getting on with your medicines.

Part 1 this tells you the purpose of this study and what will happen to you if you take part.

Why are we doing this research?

When patients go from home to hospital and from hospital back home, problems can occur with the transfer of information about a patient's medicines. In research, we already have information about how it affects patients when they leave hospital in adults, but not in children.

Explanation – what is Medicines Reconciliation?

Medicines reconciliation is "the process of creating the most accurate list possible of all medications a patient is taking including the name of the medicine, the strength and instructions of how to take it and comparing this against the doctors' list when a patient changes care settings – for example from hospital to home."

Why have my parent/carer and I been invited?

You and your parent/carer have been invited to take part because you have left hospital with medicines that will be continued by your family doctor/GP. We will be asking your parent/carer if they would like to take part in the study and will also need your agreement.

Do I have to take part?

It is up to you if you would like to agree to take part in this follow up study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign an assent (which is an agreement) form. You are free to stop taking part at any point of the study. If you decide to stop, this will not affect the care you receive.

What will happen to me if I take part?

When you decide to take part, we will arrange to visit you, or if you live further than 1 hour from the hospital, telephone you, 3weeks after you leaving hospital, We will ask your parents some questions about your medicines you take long term to find out: -

- A list of your medicines you take long term
- If your current medication list differs from how it was when you left hospital.

We will also be contacting your doctor and community pharmacist about your medication.

Please see the flow chart at the end of this information sheet to see what this involves.

How much time will this take?

The discussion with your parent's about your medications would take about 20 minutes.

We will be visiting you or phoning your parent once if you have asked for more medicines from your doctor at home. If not we may visit you again at a later time when you do. We will visit you or phone your parent two times maximum.

What are the risks and the possible benefits of taking part?

We can't see any risks involve with taking part in the interview and follow up.

We cannot promise the study will help you, but the information that we get might help us find ways to preventing medicine type problems that happen when children and young people leave hospital on medicines.

Thank you for reading so far – if you are still interested please read part 2

Part 2 – This part of the information sheet will provide more information you need to know if you want to take part

What will happen if I don't want to carry on with the study?

You can choose to withdraw at any point of the study. This will not affect your current treatment.

What if there is a problem?

Should a problem arise, the research pharmacist will refer and signpost to the most appropriate authority depending on the nature of the problem. Please talk to your parent/guardian about the problems.

Will my participation the study be kept confidential?

Yes, your participation is kept confidential.

The research pharmacist has a contract with the hospital trust and will follow and adhere to the confidentiality procedures of the hospital and will have a duty of confidentiality to you as the research participant. We will do our best to meet this duty.

Involvement of the General Practitioner/Family doctor

We will be sending your GP a letter of notification of the study. During the follow up, should we find a difference between what the doctors have prescribed to you in comparison to the medicines prescribed after discharge, we will contact your GP. Only information relating to your medication will be exchanged for this for clarification.

What will happen to the results of the research study?

Results of the research study will be written up as a report for the funding body of the study. Please note that you will not be identified in any report or publication of results. If you are interested and would like to find out the results of the study, a copy of the final report will be made available on request.

Who is organising and funding the study

The Pharmacy Practice Research Trust, an independent research charity, who supports pharmacy type research will be paying for this study.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the London Riverside Research Ethics Committee.

Thank you for reading this leaflet. Please ask any questions if you need to.

For further information: -

Please contact Mr Chi Huynh, Research Pharmacist. Telephone Email:

Page 2

Flow chart of the study

At the time of your hospital admission: - Our team pharmacist will approach you and introduce you to the study. You will have the length of the stay to decide whether or not to consent. At discharge - if you have consented and agreed to take part, the research team will obtain your contact details for follow up purposes. They will also record the medicines that you are on at discharge. At this point we will also book and arrange a suitable and convenient time for a follow up visit or a phone call 21 days after you are discharged If you have given consent and chosen to If you have given consent and chosen to be followed up 21 days after you have be followed up 21 days after you have left hospital via telephone left hospital via home visit At the pre-arranged time 21 days later The research pharmacist will ask you if The research pharmacist will visit your you have seen your GP for further home. If you have not seen the GP for supplies of medicines. If you haven't, further supplies medicines, an alternate the research pharmacist will arrange date to visit will be arranged. another time to call We will compare the medicines that you would be taking according to the information you provide (either in person or on the phone) with the hospital discharge medicines. If a difference occurs between the discharge medicines that were originally prescribed and what you would be on at the time of interview - we will contact the GP and the community pharmacist as appropriate.

Version 10.4 Last updated 30/11/2011

MERRY-PD study - Three week follow up phone call or home visit after you have left hospital



What is research? Why is this study being done?

Research is a way we try to find out the answers to questions. We want to see if children experience problems with getting medicines when they leave hospital for home. We know that your parent/carer will be helping you get the medicines so we would like to speak to them. We will ask for your parents' permission and also ask you if you would agree to taking part.

Why have I been asked to take part?

Your parent/carer and you have been asked to take part as you are going home with medicines that need a continued supply from your home doctor.

Did anyone else check the study is OK to do?

Before any research is allowed to happen, it has to be checked by a group of people called a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the London Riverside Research Ethics Committee.

Do I have to take part?

It is up to you. You can choose not to take part or change your mind at any time; this will not affect the care you receive.

What will happen to me if I take part in the research?

Please see the flow chart below

Will joining the study in help me?

We can't promise that the study will help you but the information we get might help reduce problems with medicines from happening when a child leaves hospital.

Will my medical details be kept private if I take part? Will anyone else know I'm doing this?

Nobody will know that you are taking part in this study apart from when it is needed.

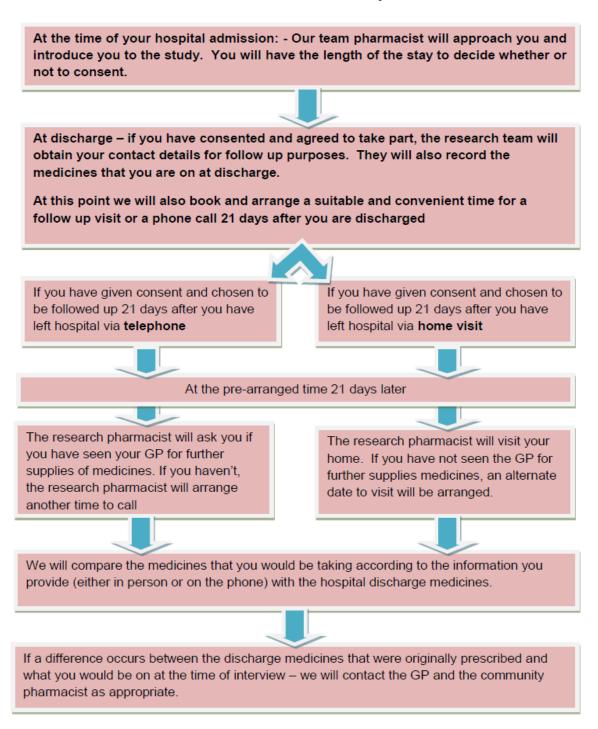
What happens if something goes wrong?

The researcher will ensure that your parent and yourself are guided to the right people who can help if possible.

Version 10.4 Last updated 30/11/2011

Page 1

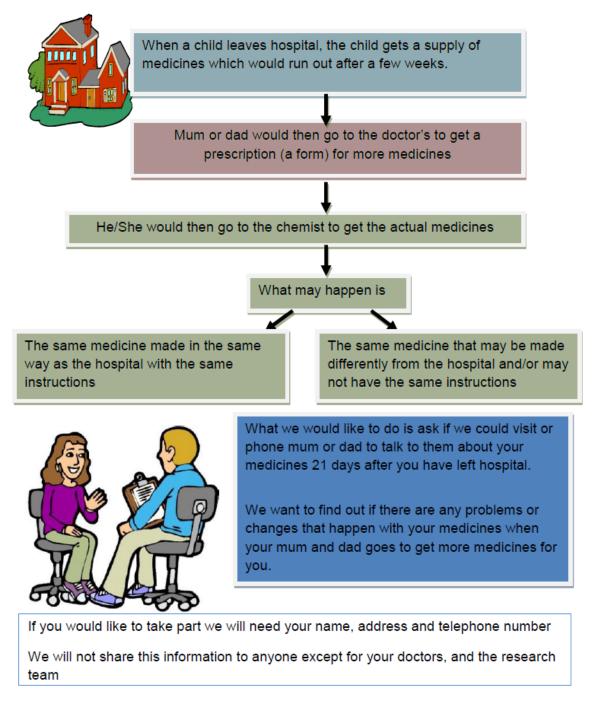
Flow chart of the study



Version 10.4 Last updated 30/11/2011

Information about the research – For young persons under 5 years

We would like to invite you to take part in the MERRY - PD study



This leaflet is intended for the parent/carer to read to the child under 5 years of age

Version 10.4 Last updated 30/11/2011

Page 2

Appendix K – MCRN Young person's advisory group feedback



MERRY Study Feedback

Under 7 year olds

<u>Positive</u>

Pictures are good

Contact details are clear - underlining and colour good for highlighting information

Colour is good

Information within boxes is easy to understand

Negative

Pictures are too detailed (e.g. the prescription pad)

Confusing title - consider placing the title in the footer in smaller font

Spelling mistake in first box (their instead of there)

The font should be made bigger

The last sentence needs clarification

The YP didn't like sentences being broken up by pictures - they found it confusing

There were words they didn't understand (e.g. medicine, surgery, chemist, G.P.)

8-11 year olds



Positive

It is in a good order from the start to finish

It is bold and clear

The layout means that it is not confusing - it is good that there are no solid blocks of text

They liked having lots of headings

They feel it is age appropriate

It is easy to read

It is very informative

Negative

They would take out the first two lines as they feel it is repetitive

They also highlighted the fact that the title was confusing - perhaps place in the footing in small print

There are words they don't understand (e.g. reconciliation and discharge)

They didn't like that the sentences were broken up as they found it too confusing - perhaps have the pictures at the end.

Use pictures that are clear - they didn't like the picture of the hospital as it seemed 'scary'

They thought the font size should be larger

12+ year olds



Positive 199

It is simple and easy to read

It is suitable for the age group

The subheadings persuade you to read the information sheet

They like the way it is presented

The contact details are clear - you would easily be able to identify who to contact

The illustrations will be helpful to those who can't read well

Negative

The illustrations should be more detailed - perhaps use real photos, this would make it more age appropriate

Some abbreviations are unclear - they don't always know what things stand for (e.g. G.P.)

'Appendix G Stage 1' should be removed as it would only confuse the patient

A flow chart might make it easy to read

Re-written introduction: Our study involves a phone call or visit 3 weeks after you have been discharged from hospital, to find out about any follow up medication you are on and any problems you are having obtaining it.

The title has lots of 'fancy words' which a young person wouldn't understand

There could be more general information about the study

Appendix L – Consent forms (for parent/carer/patient)

(Form to be on site specific headed paper)

Centre Number:

Study Number:

Patient Identification Number for this study:

CONSENT FORM

Title of Project: Medicines reconciliation research in young patients post discharge (MERRY - PD)

Name of Researcher: _____

1. I confirm that I have read and understand the information sheet dated 20/11/2011 (version 10.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the research team at the hospital, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

Name of Patient/Parent/Carer (please cross off as appropriate)	
Date	
Signature	

Name of person taking consent	
Date	
Signature	

Patient's/Parent's/Carer's copy

Researcher's copy for record

Appendix M – Sample Assent form ASSENT FORM FOR PARTICIPATION IN THE: -

Medicines Reconciliation Research in Young Patients – Post Discharge (MERRY-PD) study

To be completed by the child (or if unable, parent on their behalf) /young person to circle all they agree with:

Has somebody else explained this project to you? Yes/No

Do you understand what this project is about? Yes/No

Have you asked all the questions you want? Yes/No

Have you had your questions answered in a way you understand? Yes/No

Do you understand it's OK to stop taking part at any time? Yes/No

Are you happy to take part? Yes/No

If any answers are "no" or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below

Your Name	
Signature	
Date	

Name of pharmacist who explained the study	
Signature	
Date	

Thank you for your help.

Appendix N – Sample data collection form for Post discharge follow up

Data collection form Discharge date: Patient identifier number (researcher to complete) Formof..... TTA - Prescription (Discharge) Pharmacy amended: - Yes/No Version sent to GP: - Doctor initial order/Pharmacist's amended copy Date and Time of discharge Has the patient visited GP for further medication? Yes/No Date and time of 21 Day interview/visit: -(If no - reschedule interview/visit Date and time of rescheduled interview/visit (if patient hasn't visited GP): -Drug Name Form Dose Route Directions Duration Manufacturer Date of 21 Day Details of GP and or Source of (Brand/ (units) changes and Pharmacist intended issue Post supply (If Generic) Discharge given at unlicensed) discharge Parent's Comments discharge comments Code Difference (intentional/ (intentional/ (Yes/No) unintentional) unintentional) DD/MM/ A Omeprazole Mups 10mg Oral Dissolve 4 months London Yes Changed to Intentional (Dispersible one in 5ml and YYYY (as liquid 10mg/5ml change. tablets) of water hospital labelled) - 5ml OD. review (See comment and give 5 Mum unsure box) mls (see comment box) No Atenolol tablets 10mg oral

Data collection form

Discharge date: Patient identifier number

(researcher to complete)

Form of

Comments of changes/discrepancies (code provided in first column for discrepancies) in detail

Code	Parent's comments and explanation	GP comments and explanation	Community Pharmacist comments and explanation
Α			

Appendix O – MERRY-PD – Standard Operational Procedure for contacting GP

Stage 1: - Standard Operating procedure for researcher contacting the GP to request information on patients medication post discharge: -

- 1) Obtain the patients GP name and number from either:
 - a. EPR
 - b. Patient records
 - c. Discharge summary
 - d. The patient
- Explain that you are carrying out research project on medication issues paediatric patients experience post discharge and would like to find out information about the patients prescribed medication presently
- 3) Note down the patients medication list over the phone (using the data collection form) or if the GP refuses to provide information over the phone send a fax request and record the medications onto the data collection form
- Compare the GP list to the discharge summary and identify the discrepancies
- Contact the GP to identify which discrepancies were intentional or unintentional

Stage 1 Sample Fax request wording – GP or community Pharmacy

Name of Hospital sending fax: -

Fax number of Hospital: -

FAO to: - e.g. Surgery/Medical centre

Date of Fax: -

Dear Sir/Madam,

RE: - Patient Name: - Current prescribed medications

Following our earlier conversation, I would like to request a list of the current medications that the patient above (whom we have discharged recently) is currently taking.

The reason for this request is that we are carrying out a follow up study of patients discharge from hospital looking into the quality and standards of our hospital's discharge prescriptions in communicating medication information.

Please fax by return at your earliest convenience to the fax number provided*.

Many Thanks for your help with this

Yours sincerely

Mr Chi Huynh Honorary research pharmacist at Hospital PhD Student Centre for Paediatric Pharmacy Research The School of Pharmacy, University of London BMA/Tavistock House (Entrance A) 1st Floor Tavistock Square London WC1H 9JP

Tel: Mobile:

Appendix P – Focus group invitation Stage 3 – Focus Group: - Focus group invitation

Dear Healthcare professional,

RE: - Medicines Reconciliation Research in Young Post Discharge (MERRY-PD)

Our study group who are working with hospital are currently looking at ways to improve our current practice, and will be evaluating the way in which our hospital communicates the discharge medicines information to the GP practices within the PCT and who are from other regions but discharge from our hospital.

From a previous study, we have identified various problems that paediatric patients who have recently been discharged from hospital have experienced in terms of their medication supplies. We would like your views on the case scenarios, and would like to invite you to a focus group meeting so that we can discuss and find possible solutions to resolve medication problems post discharge.

If you would like to take part in the focus group please contact the research pharmacist either by phone...... or email...... We will also contact you in due course to confirm your participation and arrange a date for the focus group.

Yours faithfully

Mr Chi Huynh Honorary research pharmacist at Hospital PhD Student Centre for Paediatric Pharmacy Research The School of Pharmacy, University of London BMA/Tavistock House (Entrance A) 1st Floor Tavistock Square London WC1H 9JP

Tel:

Mobile:

Appendix Q – Focus group Participant information leaflet Focus group on Medicines reconciliation post hospital discharge

Purpose of study

It is known that discrepancies occur post hospital discharge, however the extent of the problem for the paediatric patient population is unknown. As GP, community pharmacist and hospital pharmacists are the healthcare professionals that have direct contact with patients on a regular basis, it is important that we find out from them the issues that they find with dealing with medicines management in children post discharge.

Aims and objectives for this focus group are to: -

- Give the healthcare professionals an opportunity to discuss and share their previous experiences with post hospital discharge medication discrepancies in children
- To gain insight into how healthcare professionals deal with medication discrepancies that occur when a medication discrepancy occurs with a paediatric patient post discharge
- To use anonymised moderate and severe discrepancies cases and root causes identified by the previous stages of the research study to create conversation and discussion on how they would intervene and who ought to be the healthcare professional who is best equipped to deal and resolve the discrepancy.

Who wants the information?

The MERRY-PD research team, looking into medicines reconciliation in children post discharge would like to find information and possible solutions to solving problems that children face for their further medication supplies. We would hope that with your participation and contributions during the group discussions, you can help us find possible answers to problems that children face as they go from hospital to home

Your help is needed

Without this focus group we would not be able to find out how your contributions, which are not normally apparent, are vital in preventing patient adverse outcomes in this patient group and this is why we would like your support.

Duration of the meeting

The focus group will take no longer than 2 hours, and you will be among a group of 6-8 other healthcare professions: - hospital pharmacists, GPs, and community pharmacists. A moderator will be present to facilitate the discussion.

How will the information be used?

The information from the focus group will be recorded and analysed. The findings will be used to help with service development of a potential intervention for reducing medication related problems in children with regards to their further medication supplies. Participants who attend this focus group will not be identified in any reports and their details will remain anonymous.

For further information and questions please contact Mr Chi Huynh, research pharmacist via email: -

Appendix R – Moderator's guide to the focus group

Aims and objectives of this focus group: -

- Give the healthcare professionals an opportunity to discuss and share their previous experiences with post hospital discharge medication discrepancies in children
- To gain insight into how healthcare professionals deal with medication discrepancies that occur when a medication discrepancy occurs with a paediatric patient post discharge
- To use anonymised moderate and severe discrepancies cases and root causes identified by the previous stages of the research study to create conversation and discussion on how they would intervene and who ought to be the healthcare professional who is best equipped to deal and resolve the discrepancy.

Welcome statement

- Thank you for participating in the focus group
- Everything that you discuss in this meeting will be confidential
- There are no right or wrong answers
- We would like to hear views from everyone
- Please feel free to share your opinions opening
- For accuracy reasons only, the recording of this group meeting will be recorded.

I will guide the discussion with questions but will hope that there will be a discussion flow from the group.

Today we are going to be talking about medication problems that children may face when they are discharged from hospital back to the GP and obtain further medication supplies from the community pharmacy.

- 1. Let's just go around and have everyone introduce themselves, and what role to they play in the care of the patient upon hospital discharge and beyond.
- 2. I would now like to ask if you have had experience of situations where a child recently discharged from hospital and on long term medication has had a problem with their medication and would like to discuss amongst each other the following issues:
 - a. At what stage was the medication problem spotted and who highlighted the problem?
 - b. What action was taken to resolve the issue?
 - c. Once the problem was sorted out how was the patient or patient's parent? Were they aware from the start that there was a problem or unaware?

- d. Did you investigate the cause of the problem and contact the person who may have contributed to the problem?
- e. Does your workplace have a system of documenting these problems?

It would be good to brainstorm the discussion and jot down the scenarios.

3. Now that we have discussed a) Situations where paediatric patients experience problems with their medications post hospital discharge –

lets discuss the types of problems that may occur that you have discussed earlier – for example a patient walks into the community pharmacy with a repeat prescription – not knowing the new antiepileptic drug prescribed is not on there until she comes back to collect the medicines.

I know this may sound repetitive, but in this part of our focus group, let's as a group discuss where you think the source of the problem has occurred and how you would deal with this case given the circumstances and what you all think would be a solution from preventing this from happening again?

- 4. Now that we've discussed our experiences of situations where children who have recently been discharged from hospital have experienced problems with their medication, lets discuss:
 - a. If you felt that you are happy with dealing with these problems with medication on a case by case basis
 - i. If you are happy I would like you all to discuss why you are happy with dealing with it case by case by reasoning?
 - ii. If you were not happy with dealing with the problems case by case, who you want to some guidance to refer to?
 - b. As we have GP, hospital pharmacists and community pharmacists we would like you to discuss, who would be the ideal healthcare professional who is suited and best placed in the post discharge process to deal with reconciling differences or resolving problems that occur when a patient is discharged back into community and why you think that way?

It would be good to brainstorm the reasons why a each HCP - GP, Hospital Pharmacist, and community pharmacist may be a good person to resolve the issues discussed 5. As a last question – I would like to ask if you can recall any incidences in your practice where a patient has had an adverse event or been clinically affected by medication problems that have occurred due to miscommunication between the hospital discharge medications and the GP medications. Please described what occurred and how was it discovered and what were the consequences and how was it dealt with.

Summarise what was discussed.

Closing

Thank you for participating in the focus group. This will help us understand a side of your profession and your contributions to preventing potential medication related adverse effects from happening.